

**EPA Reg. No. 81598-17**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

October 20, 2017

Ms. Anna Armstrong, Agent  
Rotam Limited  
c/o Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, DE 19707

Subject: Label Amendment – Updating Respirator Statement  
Product Name: Oxamyl Technical  
EPA Registration Number: 81598-17  
Application Date: October 12, 2017  
Decision Number: 534715

Dear Ms. Armstrong:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

**SEE NEXT PAGE**



Page 2 of 2  
EPA Reg. No. 81598-17  
Decision No. 534715

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Carlyn Petrella by phone at 703-347-0439, or via email at [petrella.carlyn@epa.gov](mailto:petrella.carlyn@epa.gov)

Sincerely,



Michael Walsh  
Product Manager 11  
Invertebrate & Vertebrate Branch 2  
Registration Division  
Office of Pesticide Programs

Attachment

# Oxamyl Technical

INSECTICIDE/NEMATOCIDE  
FOR FORMULATING USE ONLY

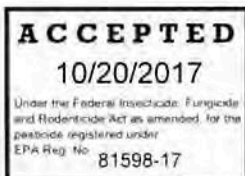
**ACTIVE INGREDIENT:**

Oxamyl

Methyl N'N'-dimethyl-N-[(methylcarbamoyl)oxy]-1-thioxamimidate..... 97.41%

**OTHER INGREDIENTS:** ..... 2.59%**TOTAL:** ..... 100.0%**BY WT.**

KEEP OUT OF REACH OF CHILDREN  
**DANGER/PELIGRO**

**POISON/VENENO**

FIRST AID	
<b>Contains an N-methyl carbamate that inhibits cholinesterase.</b>	
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger.</li> <li>Do not induce vomiting or give anything by mouth to an unconscious person.</li> </ul>
<b>IF INHALED:</b>	<ul style="list-style-type: none"> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<b>ATROPINE IS AN ANTIDOTE: SEEK MEDICAL ATTENTION AT ONCE IN ALL CASES OF SUSPECTED POISONING</b> If symptoms appear (see <b>SYMPTOMS</b> ), get medical attention. <b>SYMPTOMS:</b> Oxamyl poisoning produces effects associated with anticholinesterase activity which may include weakness, blurred vision, headache, nausea, abdominal cramps, discomfort in the chest, constriction of pupils, sweating, slow pulse, muscle tremors.	
<b>NOTE TO PHYSICIAN</b> <b>TREATMENT:</b> Atropine sulfate should be used for treatment. Administer repeated doses, 1.2 to 2.0 mg intravenously every 10 to 30 minutes until full atropinization is achieved. Maintain atropinization until the patient recovers. Artificial respiration or oxygen may be necessary. Allow no further exposure to any cholinesterase inhibitor until recovery is assured. Do not use morphine or 2-PAM.	
<b>HOT LINE NUMBER</b> Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For 24-Hour Medical Emergency Assistance (Human or Animal), call: <b>1-800-222-1222</b> . For Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), call CHEMTREC: <b>1-800-424-9300</b> .	

**Manufactured For:**

Rotam Limited  
Unit 6, 26/F Trend Centre  
29 Lee Chung Street  
Chai Wan, Hong Kong

**EPA Reg. No.: 81598-17****EPA Est. No.:****Net Contents:**

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS & DOMESTIC ANIMALS  
DANGER/POISON**

Fatal if swallowed. May be fatal if inhaled. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Do not breathe dust. Remove and wash contaminated clothing before reuse.

**HANDLE PRODUCT ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT:**

Wear a protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet. Wear chemical-resistant gloves (made of barrier laminate, butyl rubber >14 mils, nitrile rubber >14 mils, neoprene rubber >14 mils, natural rubber >14 mils, polyethylene, polyvinyl chloride (PVC) >14 mils or Viton >14 mils), chemical-resistant apron and chemical-resistant shoes, shoe coverings or boots. Wear goggles or a face shield. Wear a minimum of an elastomeric half face NIOSH approved respirator with organic vapor (OV) cartridges and a combination N, R or P filter (TC-84A); or a NIOSH approved gas mask with an OV canister (TC-14G); or a NIOSH approved powered air purifying respirator with an OV cartridge and combination HE filter (TC-23C). Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to aquatic organisms and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**PHYSICAL AND CHEMICAL HAZARDS**

Combustible. Do not use or store near heat or open flame. Keep container closed. Use with adequate ventilation.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Only for formulation into an insecticide/nematicide.

**For the following uses:**

**Terrestrial Food Crops:**

Apples, apples (non-bearing)	Peanuts
Bananas	Pear, pear (non-bearing)
Cantaloupe	Peppers
Carrots	Peppermint
Celery	Pineapple
Cherry (non-bearing)	Plantain
Citrus, citrus (non-bearing)	Potato
Cotton	Pumpkin
Cucumber	Spearmint
Eggplant	Squash
Garlic	Sweet potato
Ginger	Tomato
Honeydew melons	Watermelon
Onions (dry bulb)	Yams
Peach (non-bearing)	

**Terrestrial Non-Food Crops: Tobacco**

- Uses for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration
- Uses for experimental purposes that are in compliance with U.S. EPA requirements.

Products formulated from this product will require registration with the Environmental Protection Agency.



**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**Pesticide Storage**

Store product only in original container, in a cool, dry industrial location inaccessible to children and pets. Do not use or store in or around the home.

**Pesticide Disposal**

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Handling:**

**NONREFILLABLE CONTAINERS:** Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container  $\frac{1}{4}$  full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY**

**NOTICE:** Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of this product, which are beyond the control of ROTAM LIMITED, or Seller. The Buyer and User shall assume all such risks, and Buyer and User agree to hold ROTAM LIMITED and Seller harmless for any claims relating to such factors.

To the extent consistent with applicable law, ROTAM LIMITED warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to proper instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or ROTAM LIMITED, and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ROTAM LIMITED MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR NEITHER A PARTICULAR PURPOSE NOR ANY OTHER EXPENSES OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with applicable law, ROTAM LIMITED or Seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF ROTAM LTD AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF ROTAM LIMITED OR SELLER, THE REPLACEMENT OF THE PRODUCT.

ROTAM LIMITED and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sales and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of ROTAM LIMITED.



Submitted Electronically via Email

October 12, 2017

Document Processing Desk (**AMEND**)  
ATTN: Michael Walsh, PM No. 11  
Registration Division  
U.S. Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202-4501



Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

**Subject: Oxamyl Technical - (EPA Reg. No. 81598-17)- EPA Initiated Label Amendment**

Dear Mr. Walsh:

Wagner Regulatory Associates, Inc., as agent for Rotam Limited (EPA Co. Number 81598), respectfully submits the attached label amendment as required by EPA Correspondence Dated October 10, 2017.

In support of this submission, the following documents are attached:

- Letter from Rotam Limited. appointing WRA, Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Draft labeling
- Certification with Respect to Label Integrity
- Reference copy of Agency Correspondence with required changes

Please do not hesitate to contact me should you have any questions regarding this submission. Thank you in advance.

Respectfully submitted,

Anna Armstrong  
Agent for Rotam Limited  
Tel: 302-510-0039 email: [anna@wagnerreg.com](mailto:anna@wagnerreg.com)

Enclosures



United States  
**Environmental Protection Agency**  
 Washington, DC 20460

☐ **Registration**

OPP Identifier Number

☒ **Amendment**
☐ **Other**

### Application for Pesticide - Section I

1. Company/Product Number 81598-17	2. EPA Product Manager Michael Walsh	3. Proposed Classification  <input checked="" type="checkbox"/> None      Restricted
4. Company/Product (Name) Rotam Limited / <b>Oxamyl Technical</b>	PM# 11	
5. Name and Address of Applicant (Include Zip Code)  Rotam Limited c/o Wagner Regulatory Associates, Inc. P.O. Box 640, 7217 Lancaster Pike, Suite A Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No.: 352-400 Product Name: DuPont Oxamyl Technical 42 Insecticide/Nematicide	

### Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

**EPA Initiated Label Amendment per EPA Correspondence dated October 10, 2017**

### Section - III

1. <b>Material This Product Will Be Packaged In:</b>				2. <b>Type of Container</b>	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
	If "Yes"      No. per Unit Packaging wt.      container	If "Yes"      No. per Package wt      container		<input checked="" type="checkbox"/> Plastic	
* <b>Certification must be submitted</b>				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) HDPE lined bags	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container bulk		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

### Section - IV

1. <b>Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</b>					
Name Anna Armstrong		Title Agent for Rotam Limited		Telephone No. (Include Area Code) (302) 510-0039 or anna@wagnerreg.com	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received  <div style="text-align: center;">(Stamped)</div>
2. Signature 		3. Title Agent for Rotam Limited			
4. Typed Name Anna Armstrong		5. Date October 12, 2017			

This is a reproduction of EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

May 23, 2017

To: Whom it May Concern

Re: ROTAM LIMITED (Firm Number: 81598)

This letter serves as notification that **ROTAM LIMITED** has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as the Agent on our company's behalf regarding state and/or federal regulatory matters as determined by **ROTAM LIMITED**. The following employees of Wagner Regulatory Associates, Inc. are authorized to act on our behalf:

James Wagner  
Email: [james@wagnerreg.com](mailto:james@wagnerreg.com)  
Phone: 302-635-7290

Cheryl Wagner  
Email: [cheryl@wagnerreg.com](mailto:cheryl@wagnerreg.com)  
Phone: 302-635-7289

Anna Armstrong  
Email: [anna@wagnerreg.com](mailto:anna@wagnerreg.com)  
Phone: 302-510-0039

Barbarette Young-Henry  
Email: [barbarette@wagnerreg.com](mailto:barbarette@wagnerreg.com)  
Phone: 302-635-7279

Carrie Nolan  
Email: [carrie@wagnerreg.com](mailto:carrie@wagnerreg.com)  
Phone: 302-635-7632

Kt Woodall  
Email: [ktwoodall@wagnerreg.com](mailto:ktwoodall@wagnerreg.com)  
Phone: 302-635-7283

Catherine Parmeter  
Email: [Catherine@wagnerreg.com](mailto:Catherine@wagnerreg.com)  
Phone: 410-920-8756

Correspondence can be addressed to any of the above employees at:

Wagner Regulatory Associates  
P. O. Box 640  
Hockessin, DE 19707-0640

Thank you for your time and assistance. Please feel free to contact Wagner Regulatory Associates should you have any questions.

Respectfully submitted,

For and on behalf of  
**ROTAM LIMITED**  
.....  
*Authorized Signature*

Yifan Wu  
Head of Research, Development and Registration Division  
ROTAM LIMITED  
Tel: 86-512-5790 3076  
Fax: 86-512-5771 8692  
Email: yifanwu@rotam.com

cc: WRA, Inc.



# Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
81598-17	October 12, 2017	81598-17.20171012.V1

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

  
Signature

October 12, 2017  
Date

Anna Armstrong  
Name (typed)

Agent for Rotam Limited  
Title

# PROCESSING REQUEST

Reg # 81598-17

Decision # 523784

Description: **Expedited for Onion Growers**

**Rotam – New Oxamyl Technical Product**

**PRIA Due Date: 10/16/2017 (completed more than 6 months and 3 weeks before due date)**

**Electronic Label & Letter**

(see PPLS):

**OR**

**Non Electronic**

**Label & Letter**

(Scanning required):

☒ Dated: 3/24/17

☐ Dated:

\*\*\*Only one label type should be selected\*\*\*

**Other Materials Sent** (see jacket):

☒ New CSF(s) Dated: Basic CSF: 11/21/2016

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

**Reviewer: Michael Walsh, PM 11 for Carlyn Petrella**

**Division: RD/IVB2**

**Phone: 308-2972**

**Date: 3/24/2017**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

October 10, 2017

Mr. James Wagner, Agent  
Rotam Limited  
c/o Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, DE 19707

Subject: Agency Initiated Action – Updating Respirator Requirement  
Product Name: Oxamyl Technical  
EPA Registration Number: 81598-17

Dear Mr. Wagner:

Upon review of the product record, it has come to the Agency's attention that the following changes should be made to the product label:

- Replace the respirator requirement that now reads "Wear a NIOSH approved particulate respirator with any N, R or P filter with NIOSH approval number prefix TC-84A; or a NIOSH approved powered air purifying respirator with HE filter with NIOSH approved number prefix TC-21C." with "Wear a minimum of an elastomeric half face NIOSH approved respirator with organic vapor (OV) cartridges and a combination N, R or P filter (TC-84A); or a NIOSH approved gas mask with an OV canister (TC-14G); or a NIOSH approved powered air purifying respirator with an OV cartridge and combination HE filter (TC-23C).

Please submit a revised label within 10 business days of the date of this letter. If you have any questions, please contact Carlyn Petrella by phone at (703) 347-0439, or via email at [petrella.carlyn@epa.gov](mailto:petrella.carlyn@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Walsh", is positioned above the typed name.

Michael Walsh  
Product Manager 11  
Invertebrate & Vertebrate Branch 2  
Registration Division  
Office of Pesticide Programs



# **Note to: ITRMD**

**81598-RT / 81598-17**

**A legal challenge based on  
Data Compensation is likely for this  
product.**

**Please do not remove any of the  
documents in the jacket without first  
contacting the Product Manager for  
Oxamyl.**

**Thank you.**

**Michael Walsh, Tel: 308-2972**





U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Registration Division (7505P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

EPA Reg. Number:

81598-17

Date of Issuance:

3/24/17

Term of Issuance:

Conditional

Name of Pesticide Product:

Oxamyl Technical

Name and Address of Registrant (include ZIP Code):

James Wagner, Agent  
Rotam Limited  
c/o Wagner Regulatory Associates  
PO Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Michael Walsh, Product Manager 11  
Invertebrate & Vertebrate Branch #2  
Registration Division (7505P)

Date:

3/24/17

2. You are required to comply with the data requirement described in the DCI identified below:

a. Oxamyl GDCI-103801

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

3. Make the following label changes before you release the product for shipment:

- Revise the EPA Registration Number to read, "EPA Reg. No. 81598-17."

4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 11/21/2016

If you have any questions, please contact Carlyn Petrella by phone at 703-347-0439, or via email at [petrella.carlyn@epa.gov](mailto:petrella.carlyn@epa.gov).

Attachment



# Oxamyl Technical

INSECTICIDE/NEMATICIDE  
FOR FORMULATING USE ONLY**ACTIVE INGREDIENT:**

Oxamyl

Methyl N'N'-dimethyl-N-[(methylcarbamoyl)oxy]-1-thiooxamimidate..... 97.41%

**OTHER INGREDIENTS:** ..... 2.59%**TOTAL:** ..... 100.0%

BY WT.

**KEEP OUT OF REACH OF CHILDREN  
DANGER/PELIGRO****POISON/VENENO****ACCEPTED**

03/24/2017

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 81598-17**FIRST AID****Contains an N-methyl carbamate that inhibits cholinesterase.**

<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger.</li> <li>• Do not induce vomiting or give anything by mouth to an unconscious person.</li> </ul>
<b>IF INHALED:</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>

**ATROPINE IS AN ANTIDOTE: SEEK MEDICAL ATTENTION AT ONCE IN ALL CASES OF SUSPECTED POISONING**If symptoms appear (see **SYMPTOMS**), get medical attention.**SYMPTOMS:** Oxamyl poisoning produces effects associated with anticholinesterase activity which may include weakness, blurred vision, headache, nausea, abdominal cramps, discomfort in the chest, constriction of pupils, sweating, slow pulse, muscle tremors.**NOTE TO PHYSICIAN****TREATMENT:** Atropine sulfate should be used for treatment. Administer repeated doses, 1.2 to 2.0 mg intravenously every 10 to 30 minutes until full atropinization is achieved. Maintain atropinization until the patient recovers. Artificial respiration or oxygen may be necessary. Allow no further exposure to any cholinesterase inhibitor until recovery is assured. Do not use morphine or 2-PAM.**HOT LINE NUMBER**Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For 24-Hour Medical Emergency Assistance (Human or Animal), call: **1-800-222-1222**. For Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), call CHEMTREC: **1-800-424-9300**.**Manufactured For:**Rotam Limited  
Unit 6, 26/F Trend Centre  
29 Lee Chung Street  
Chai Wan, Hong Kong

EPA Reg. No.: 81598-XX

EPA Est. No.:

Net Contents:

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS & DOMESTIC ANIMALS**  
**DANGER/POISON**

Fatal if swallowed. May be fatal if inhaled. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Do not breathe dust. Remove and wash contaminated clothing before reuse.

**HANDLE PRODUCT ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT:**

Wear a protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet. Wear chemical-resistant gloves (made of barrier laminate, butyl rubber >14 mils, nitrile rubber >14 mils, neoprene rubber >14 mils, natural rubber >14 mils, polyethylene, polyvinyl chloride (PVC) >14 mils or Viton >14 mils), chemical-resistant apron and chemical-resistant shoes, shoe coverings or boots. Wear goggles or a face shield. Wear a NIOSH approved particulate respirator with any N, R or P filter with NIOSH approval number prefix TC-84A; or a NIOSH approved powered air purifying respirator with HE filter with NIOSH approved number prefix TC-21C. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to aquatic organisms and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**PHYSICAL AND CHEMICAL HAZARDS**

Combustible. Do not use or store near heat or open flame. Keep container closed. Use with adequate ventilation.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Only for formulation into an insecticide/nematicide.

**For the following uses:**

**Terrestrial Food Crops:**

Apples, apples (non-bearing)  
 Bananas  
 Cantaloupe  
 Carrots  
 Celery  
 Cherry (non-bearing)  
 Citrus, citrus (non-bearing)  
 Cotton  
 Cucumber  
 Eggplant  
 Garlic  
 Ginger  
 Honeydew melons  
 Onions (dry bulb)  
 Peach (non-bearing)

Peanuts  
 Pear, pear (non-bearing)  
 Peppers  
 Peppermint  
 Pineapple  
 Plantain  
 Potato  
 Pumpkin  
 Spearmint  
 Squash  
 Sweet potato  
 Tomato  
 Watermelon  
 Yams

**Terrestrial Non-Food Crops: Tobacco**

- Uses for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration
- Uses for experimental purposes that are in compliance with U.S. EPA requirements.

Products formulated from this product will require registration with the Environmental Protection Agency.



**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**Pesticide Storage**

Store product only in original container, in a cool, dry industrial location inaccessible to children and pets. Do not use or store in or around the home.

**Pesticide Disposal**

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Handling:**

**NONREFILLABLE CONTAINERS:** Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY**

**NOTICE:** Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of this product, which are beyond the control of ROTAM LIMITED, or Seller. The Buyer and User shall assume all such risks, and Buyer and User agree to hold ROTAM LIMITED and Seller harmless for any claims relating to such factors.

To the extent consistent with applicable law, ROTAM LIMITED warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to proper instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or ROTAM LIMITED, and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ROTAM LIMITED MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR NEITHER A PARTICULAR PURPOSE NOR ANY OTHER EXPENSES OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with applicable law, ROTAM LIMITED or Seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF ROTAM LTD AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF ROTAM LIMITED OR SELLER, THE REPLACEMENT OF THE PRODUCT.

ROTAM LIMITED and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sales and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of ROTAM LIMITED.

## Walsh, Michael

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**From:** Walsh, Michael  
**Sent:** Thursday, February 02, 2017 10:06 AM  
**To:** McCall, Deborah  
**Cc:** Petrella, Carlyn; Rate, Debra  
**Subject:** RE: Oxamyl questions

Hi Debbie.

I went back through my email in-box. I did miss the email from Alton Sparks (Entomologist, University of Georgia) regarding the pending oxamyl new product actions. In his email to me, he mentioned a request from one of their largest growers to pursue a Section 18 for all of the vegetable crops listed on DuPont's end-use oxamyl product label. He also noted the pending generic new product applications from Rotam in his email to me. Mr. Sparks asked if the Rotam end-use product label would have all of the uses seen on the DuPont label making the request for a Section 18 unnecessary.

As you know, there are several issues with oxamyl production and with the pending Rotam new product applications for a technical product, manufacturing use product, and two end-use products. The issues are as follows:

- **Oxamyl is Not Currently Available** - Following a fatal accident a few years ago at DuPont's oxamyl production facility in Texas, the company has been unable to produce oxamyl. This was confirmed in our meeting with DuPont last year. At that time, DuPont also explained that they had been contacted by Florida Dept of Ag and Consumer Services, and could not work with Florida on a Section 18/24C because the company was unable to locate a source of oxamyl, and the oxamyl supply chain was exhausted. At last check, no oxamyl products were being produced.
- **Data Compensation Concerns** - DuPont contacted RD to express their concern that Rotam had submitted applications for a new oxamyl products. Rotam also has submitted applications for a new MUP and two new end-use products. At that time, DuPont had not been offered any type compensation, which they believe is due to them for reg review data. IVB2 met with OGC yesterday to discuss the new Rotam applications and issues with data compensation. In a written response yesterday, OGC indicated that IVB2 can contact Rotam to ask for verification that an offer was made to and received by DuPont. I would like to discuss this with you before contacting Rotam.
- **DuPont Meeting** - DuPont has requested a pre-registration meeting for their new source oxamyl. As of my communications with the company yesterday, they are receiving their lab reports for the new source and would like to walk-thru their submission with us. I expect the matter of data compensation to come up during the meeting.

### Status of Oxamyl Applications:

- **DuPont** - As of yesterday, DuPont's new source application has not yet been submitted, though IVB2 plans to meet with DuPont shortly regarding their new oxamyl source. Data comp is expected to be part of the discussion.
- **Rotam** - After the 21-Day Screen, the Rotam new product applications were received by IVB2 on 12/22/2016 with the results of the 11-3 review provided a day or two later. As you know, the new product jackets coming to RD often do not contain a complete set of submission documents. So, I printed out the materials for each of the product jackets, reviewed the submissions, checked for exclusive use claims, discussed the submissions with you, and then provided the submission to the reviewer for routing to CITAB Chemistry and Acute Tox. The actions are currently being screened by CITAB with screen results expected by 2/ 17/2017. All four Rotam actions (tech, MUP, two end-use products) have a Last Possible CITAB Science Due Date of 8/17/2017 and the same PRIA Due Date of 10/16/2017.....provided we can resolve the data comp issues, and there is no challenge to the registration from DuPont.

Decision Seq: 523784	Action Code: 33,NEW PRODUCT;MUP OR END USE PRODUCT WITH UI		...	?	Decision Status
FFS Start Date: 14-Dec-2016	Tentative Ind: No	Start/Stop Clock	FQPA Clock:		Tracking
Due Date: 16-Oct-2017	75-Day Due Date:	Days Elapsed:			
OPP Target Due Date:	21-Day Due Date: 14-Dec-2016	FFS Original Decision:	...	FFS Letters	
Negotiated Due Date:	90-Day Due Date: 14-Mar-2017			Action Code History	
Registrant Response Due Date:	Predecisional Due Date: 02-Oct-2017	Add to Bundle?	Secondary Decision		
Current Status: CLOSED (24-Mar-2017)	Bundle ID: BI-10349		Decision Bundle		
<input checked="" type="checkbox"/> Decision Ownership <input checked="" type="checkbox"/> Receipts <input checked="" type="checkbox"/> Data Package <input type="checkbox"/> Reduced Risk <input checked="" type="checkbox"/> Meetings & Milestones <input checked="" type="checkbox"/> FFS Information					
<input checked="" type="checkbox"/> 75 Day Letters <input checked="" type="checkbox"/> 45/90 Day Screen <input type="checkbox"/> Primary Decisions <input type="checkbox"/> Decision Milestone					
<input checked="" type="checkbox"/> FFS Negotiated Due Dates <input checked="" type="checkbox"/> OPP Target Due Date <input type="checkbox"/> Decision Comments					

**EXPEDITED - ACTION COMPLETED 6 MONTHS + 3 WEEKS BEFORE PRIA DATE:**

This is a Rotam Limited new oxamyl product application and is associated with:  
- Parent: 81598-RT (THIS PRODUCT IS PARENT); -Children: 81598-RA (MUP);  
83100-LE (end-use); 83100-LG (end-use). NOTE: Per management, HED and EFED  
review not required. DuPont/Patricia Devine contacted the PM by phone indicating that  
Rotam has not yet made an Offer to Pay, and that DuPont believes they are due  
compensation for oxamyl data generated for registration review. Per OGC's  
recommendation, Rotam's agent was asked to provide the letters and confirm receipt for  
Generic Data Offer to Pay. A complete set of letters and signed certified mail cards was  
provided. RD not aware of any data comp issues at registration. See jacket for details.

RESPIRATOR DETERMINED BY ACUTE TOX REVIEW



## Walsh, Michael

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**From:** Petrella, Carlyn  
**Sent:** Thursday, March 16, 2017 2:13 PM  
**To:** Walsh, Michael  
**Subject:** FYI FW: Oxamyl

Hi Mike.

DCI is still open for Oxamyl, so will be a conditional registration.

Thanks,

Carlyn

**From:** Piansay, Maria  
**Sent:** Thursday, March 16, 2017 2:00 PM  
**To:** Petrella, Carlyn <Petrella.Carlyn@epa.gov>  
**Subject:** RE: Oxamyl

Hi Carlyn - sorry it took a while to respond. I told you over the phone this morning that I would check on the status of the DCI and what I found out is there is one data gap that the registrant is still trying to fulfill (a pollinator study), therefore, I can tell you for sure that the DCI has not been closed for oxamyl.

Thank you and if you have more questions, let me know.  
Maria

**From:** Petrella, Carlyn  
**Sent:** Wednesday, March 15, 2017 10:01 AM  
**To:** Piansay, Maria <Piansay.Maria@epa.gov>  
**Cc:** Walsh, Michael <Walsh.Michael@epa.gov>  
**Subject:** Oxamyl

Hi Maria.

Just a few things regarding oxamyl.

I wanted you to know that RD recently approved a new source of oxamyl for DuPont. IVB2 also has five new product applications pending for oxamyl products. Four of the actions are from Rotam and one is from Orion. They have various PRIA due dates, but RD is expediting a few of the actions to make oxamyl available to growers as soon as possible.

I also wanted to know if there are any open DCIs for oxamyl. I think the DCI is closed as closed as of 2013, but I just wanted to be sure since we will use the information to determine the type of registration - - conditional or unconditional.

Please let me know as soon as possible about the DCIs.

Many thanks.

Carlyn

OPEN DCI =  
CONDITIONAL REGISTRATION



## Petrella, Carlyn

---

**From:** Anna Armstrong <Anna@wagnerreg.com>  
**Sent:** Tuesday, March 14, 2017 11:20 AM  
**To:** Petrella, Carlyn  
**Subject:** RE: EPA File Symbol 81598-RT

Hi Carlyn – thanks. Glad you didn't have to go in. It is nasty out with the ice.

I am hopeful that we will have the labels done today! May be wishful thinking – I have the tech label done. The product is offered in a polyethylene lined fiber container.

Thank you for the heads up about your absence. I hope all is ok with you.

Yes, it will be ok to send the tox reviews by email. I understand that they are CBI and give permission for you to send by email.

Thank you very much.  
Anna

**From:** Petrella, Carlyn [mailto:Petrella.Carlyn@epa.gov]  
**Sent:** Tuesday, March 14, 2017 11:13 AM  
**To:** Anna Armstrong <Anna@wagnerreg.com>  
**Subject:** RE: EPA File Symbol 81598-RT

Hi Anna.

It's pretty icy down here. I'm working from home today. I think most everyone is today.

I can send you the tox reviews for the two products if that will help. They are CBI though, and we can't guarantee our email is secure. I can password protect them, and send the password along separately, but there is some risk involved. I can get those to you tomorrow morning when I am back in the office if that will be helpful.

Also, as an FYI, my last day in the office for a while is March 22. It'd be great if we can get these labels finished up before then, because I'm not sure who will be available to work on them if I don't finish them up.

Thanks for your time,

Carlyn

**From:** Anna Armstrong [mailto:Anna@wagnerreg.com]  
**Sent:** Tuesday, March 14, 2017 10:58 AM  
**To:** Petrella, Carlyn <Petrella.Carlyn@epa.gov>  
**Subject:** RE: EPA File Symbol 81598-RT

Hi Carlyn,  
Thanks so much. I really appreciate. I believe the technical is in a fiber lined container – I will confirm ASAP.

How is the weather down your way? We are in Delaware and some snow – but a lot of ice. Our office is closed today – but I work from home except for on Mondays ...☺

I will get this label back to you hopefully by the end of the day. Jim also wants me to respond to the input from the toxicity review – so when I send the label again – I will make those comments.

Stay safe in the weather.  
Take care,  
Anna

**From:** Petrella, Carlyn [<mailto:Petrella.Carlyn@epa.gov>]  
**Sent:** Tuesday, March 14, 2017 10:56 AM  
**To:** Anna Armstrong <[Anna@wagnerreg.com](mailto:Anna@wagnerreg.com)>  
**Subject:** RE: EPA File Symbol 81598-RT

Hi Anna.

Thanks for the question. The below language looks good, but a question, is your container metal? If it is metal, remove the reference to incineration and burning. The statement can end with the sentence "Then offer for recycling if available, or puncture and dispose of in a sanitary landfill."

Because this is a tox category 1 product, that statement also needs the header "Container Handling" directly above those directions.

Please let me know if you need any more guidance.

Thank you,

Carlyn

**From:** Anna Armstrong [<mailto:Anna@wagnerreg.com>]  
**Sent:** Tuesday, March 14, 2017 10:39 AM  
**To:** Petrella, Carlyn <[Petrella.Carlyn@epa.gov](mailto:Petrella.Carlyn@epa.gov)>  
**Subject:** RE: EPA File Symbol 81598-RT

Hi Carlyn,

I am working on the label and had a question for you. I am not sure I understand what specific language for the Storage and Disposal language and wanted to confirm before we have another iteration. Is the below language what you are looking for?

Thanks,  
Anna

"Nonrefillable container: Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke."

**From:** Petrella, Carlyn [<mailto:Petrella.Carlyn@epa.gov>]  
**Sent:** Monday, March 13, 2017 10:33 AM  
**To:** Anna Armstrong <[Anna@wagnerreg.com](mailto:Anna@wagnerreg.com)>  
**Cc:** Walsh, Michael <[Walsh.Michael@epa.gov](mailto:Walsh.Michael@epa.gov)>; James Wagner <[jmw@wagnerreg.com](mailto:jmw@wagnerreg.com)>; Kt Woodall <[ktwoodall@wagnerreg.com](mailto:ktwoodall@wagnerreg.com)>  
**Subject:** RE: EPA File Symbol 81598-RT

Hi Anna.

The guidance from our tox team, and the label review manual for Tox category 1, 2 and 3 in the "If Swallowed" section of the first aid information, states "Do not induce vomiting unless told to by a poison control center or doctor." The DuPont label is out of date, and will be corrected as their label is updated.

Please update the First Aid box for 81598-RT accordingly.

Also, in the attached label, the Storage and Disposal box does not contain all the necessary information for a Tox category 1 product. Please refer to Ch. 13 of the Label Review Manual and update the Storage and Disposal box.

Please let me know if you have any questions.

Thank you,

Carlyn

**From:** Anna Armstrong [<mailto:Anna@wagnerreg.com>]  
**Sent:** Wednesday, March 08, 2017 10:47 AM  
**To:** Petrella, Carlyn <[Petrella.Carlyn@epa.gov](mailto:Petrella.Carlyn@epa.gov)>  
**Cc:** Walsh, Michael <[Walsh.Michael@epa.gov](mailto:Walsh.Michael@epa.gov)>; James Wagner <[jmw@wagnerreg.com](mailto:jmw@wagnerreg.com)>; Kt Woodall <[ktwoodall@wagnerreg.com](mailto:ktwoodall@wagnerreg.com)>; Anna Armstrong <[Anna@wagnerreg.com](mailto:Anna@wagnerreg.com)>  
**Subject:** RE: EPA File Symbol 81598-RT

Hi Carlyn,  
Thank you again for this review and information.

We have made the revisions as you requested, however I do want to make two comments:

- 1) Regarding the comment in the first aid to revise the "IF SWALLOWED" language per the tox review – DuPont's label has the induce vomiting statement. Oxamyl is an incredibly toxic product, that is very fast acting and as indicated by the toxicity data, it can be fatal if swallowed. From a toxicology standpoint there are arguments that can be made to induce vomiting in the event that there would be ingestion so to remove the product as quickly as possible from the body. The idea is that even if there would be additional burning of the esophagus, digestive lining or issues with inducing the vomiting, that the product is so inherently toxic it is better to remove from the body with vomiting as quickly as possible (waiting to call a poison control center and obtain the appropriate information would cost valuable time). We are concerned that if we have a different statement than that of the DuPont label, that this could lead to human safety issues, confusion at the State level and also confusion at the poison control center should an incident arise. Therefore, we respectfully request to leave the first aid statement for "IF SWALLOWED" as is. Please let me know your thoughts on this.
- 2) Thank you for your explanation on the crops groups. We understand this and agree. However, I wanted to point out that in removing the "Tuberous and corm vegetables (subgroup 1C)", we added back in "sweet potatoes" and "yams" since these are on the me-too DuPont label and are also crops on the end use Oxamyl product pending registration.

Again – I want to thank you and your team for efforts in expediting this registration. We will work to process additional label comments as quickly as possible.

Thanks and take care,  
Anna

*Anna Armstrong*

Registration Manager  
Wagner Regulatory Associates, Inc.  
7217 Lancaster Pike, Suite A  
Hockessin, DE 19707  
302-510-0039  
[anna@wagnerreg.com](mailto:anna@wagnerreg.com)

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**From:** Petrella, Carlyn [<mailto:Petrella.Carlyn@epa.gov>]  
**Sent:** Tuesday, March 7, 2017 3:31 PM  
**To:** Anna Armstrong <[Anna@wagnerreg.com](mailto:Anna@wagnerreg.com)>  
**Cc:** Walsh, Michael <[Walsh.Michael@epa.gov](mailto:Walsh.Michael@epa.gov)>; James Wagner <[jmw@wagnerreg.com](mailto:jmw@wagnerreg.com)>  
**Subject:** RE: EPA File Symbol 81598-RT

Hi Anna.

As part of your submission, you cited a product for labelling which does not include these uses. No EPA registration numbers have been provided of other MUP products that support these additional use sites.

Please understand that these actions are being expedited. As such, adding crops or use sites not seen on other MUP products cannot be considered at this time. If you would like to add crops at a later date, that can be considered under a separate submission.

The tox review for this product was completed so I have added some additional comments surrounding the first aid box and other tox statements. Please let me know if you have any questions on the new comments.

Please remove the highlighted use sites from the label and submit a revised label by COB Friday, making all the requested changes.

This label has not yet gone to the Product Manager for review, so one more set of comments may be forthcoming after I review your updated label.

Please let me know if you have any questions.

Thank you,

Carlyn



**From:** Anna Armstrong [<mailto:Anna@wagnerreg.com>]  
**Sent:** Tuesday, March 07, 2017 1:48 PM  
**To:** Petrella, Carlyn <[Petrella.Carlyn@epa.gov](mailto:Petrella.Carlyn@epa.gov)>  
**Cc:** Walsh, Michael <[Walsh.Michael@epa.gov](mailto:Walsh.Michael@epa.gov)>; James Wagner <[jmw@wagnerreg.com](mailto:jmw@wagnerreg.com)>  
**Subject:** RE: EPA File Symbol 81598-RT

Hi Carlyn

Thanks very much for the label edits. We do have a question regarding the removal of the 'citrus crop group 10', the 'bell and non-bell' from the peppers and the 'tuberous and corm vegetables (subgroup 1C). There are tolerances established for each of these – is there a reason why they cannot be listed?

Thank you very much,  
Anna

**From:** Petrella, Carlyn [<mailto:Petrella.Carlyn@epa.gov>]  
**Sent:** Tuesday, March 7, 2017 8:29 AM  
**To:** Anna Armstrong <[Anna@wagnerreg.com](mailto:Anna@wagnerreg.com)>  
**Cc:** Walsh, Michael <[Walsh.Michael@epa.gov](mailto:Walsh.Michael@epa.gov)>; James Wagner <[jmw@wagnerreg.com](mailto:jmw@wagnerreg.com)>  
**Subject:** EPA File Symbol 81598-RT

Hi Anna.

Attached please find initial label comments for EPA File Symbol 81598-RT.

Please note, the tox review for this product is not yet complete. Therefore additional label changes may be necessary.

Please let me know if you have any questions.

Thank you,

Carlyn

\*\*\*\*\*

Carlyn Petrella  
Biologist  
Invertebrate & Vertebrate Branch 2  
Office of Pesticide Programs  
U.S Environmental Protection Agency  
Tel: 703-347-0439



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

March 6, 2017

**MEMORANDUM:**

Subject: Name of Pesticide Product: OXAMYL TECHNICAL  
EPA Reg. No. /File Symbol: 81598-RT  
DP Barcode: DP 437747  
Decision No.: 523784  
Action Code: R333  
Submission: #995323  
E-Sub: #15645  
PC Code: 103801 (Oxamyl: 97.41%)

From: Byron T. Backus, Ph.D., Toxicologist  
CITAB  
Registration Division (7505P)

*Byron T. Backus*  
*March 6, 2017*

Through: P.V. Shah, Ph.D., Branch Chief  
CITAB  
Registration Division (7505P)

*P.V. Shah*  
*3/6/2017*

To: Carlyn Petrella / Richard Gebken, RM 11  
IVB2  
Registration Division (7505P)

Registrant: ROTAM LIMITED

**FORMULATION FROM PROPOSED LABEL:**

Active Ingredient(s):

103801 Oxamyl

by wt.

Methyl N'N'-dimethyl-N-[(methylcarbamoyl)oxy]-1-thiooxamimidate 97.41%

Other Ingredients:

TOTAL

2.59%  
100.00%

**ACTION REQUESTED:** "ASSOCIATED ACTIONS: 81598-RA; 83100-LE; 83100-LG...  
CITAB Acute Toxicology: Please note that this Oxamyl Technical product is the parent to the

three other actions cited above, and that all actions should be reviewed together. Please review all of the attached information and determine acceptability for registration... All documents associated with this action are available in Documentum...”

**BACKGROUND:** The material available to CITAB includes a copy of a cover letter dated November 21, 2016, a data matrix (dated 11/21/2016), a proposed label (with the signal word DANGER and the skull and crossbones motif), a basic CSF (dated 11/21/2016), and 6 acute toxicity studies (MRIDs 500878-05 through -10, consistent with the citations on p. 2 of the data matrix) which are available in Documentum.

#### **COMMENTS AND RECOMMENDATIONS:**

1. CITAB has reviewed the 6 acute toxicity studies in MRIDs 500878-05 through -10. All six studies have been classified as acceptable.
2. In the dermal irritation study in MRID 50087809 the study report states that 0.5 g test material (mixed “with minimum quantity of water”) was applied to one 6 cm x 6 cm clipped intact dose site on each of the 3 NZW rabbits. The 870.2500 guidelines specify that the test substance should be applied to an area of approximately 6 cm<sup>2</sup> (~2.5 cm x ~2.5 cm). No irritation was observed (all irritation scores were zero at 1, 24, 48 and 72 hours). CITAB concludes that the study is acceptable, with assignment to toxicity category III for dermal irritation.
3. Based on the results from the acute toxicity studies, the following is the acute toxicity profile for 81598-RT:

Oral LD <sub>50</sub> (rat)	Toxicity Category I	MRID 50087805	Acceptable
Dermal LD <sub>50</sub> (rat)	Toxicity Category III	MRID 50087806	Acceptable
Inhalation LC <sub>50</sub> (rat)	Toxicity Category II	MRID 50087807	Acceptable
Eye Irritation (rabbit)	Toxicity Category IV	MRID 50087808	Acceptable
Dermal Irritation (rabbit)	Toxicity Category III*	MRID 50087809	Acceptable
Dermal sensitization (LLNA)	Negative	MRID 50087810	Acceptable

\*Although no irritation was observed, the report states that the test material was applied to a 6 cm x 6 cm dose site. The 870.2500 guidelines specify that the test substance should be applied to an area of approximately 6 cm<sup>2</sup> (~2.5 cm x ~2.5 cm). CITAB concludes the study is acceptable, with assignment to toxicity category III for dermal irritation.



4. Based on the acute toxicity profile given above, as well as information from the proposed label and CSF, the following is the precautionary and first aid labeling for 81598-RT, as obtained from the Label Review System:

**PRODUCT ID #:** 081598-00017

**PRODUCT NAME:** OXAMYL TECHNICAL

**CONTAINS AN N-METHYL CARBAMATE THAT INHIBITS CHOLINESTERASE**

**PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** DANGER POISON ☠

**Hazards to Humans and Domestic Animals:**

Fatal if swallowed. May be fatal if inhaled. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Do not breathe dust. Remove and wash contaminated clothing before reuse. Wear long-sleeved shirt and long pants, socks, shoes, and gloves.

**First Aid:**

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a Note to Physician which addresses the category I Acute Oral Toxicity. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

NOTE TO PHYSICIAN: Note to CRM/PM/Registrant: The proposed label should contain a "Note to Physician" which addresses the presence of a cholinesterase inhibitor. The following statements are

suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

5. The registrant has proposed a First Aid statement for if swallowed that includes: "Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger." This should be replaced with the First Aid statement from the Label Review System which includes: "Do not induce vomiting unless told to by a poison control center or doctor."
6. The registrant has proposed a first aid statement addressing eye exposure. This is acceptable.
7. The current respirator recommendation (Label Review Manual: Chapter 10 pages 11-12) for a product formulated and applied as a solid is "A NIOSH approved particulate respirator with any N, R or P filter with NIOSH approval number prefix TC-84A; or a NIOSH approved powered air purifying respirator with HE filter with NIOSH approval number prefix TC-21C."
8. All acute toxicity data requirements for the registration of 81598-RT have been satisfied.
9. See the next page of this review for the Amended Labeling Language (as specified in Table 8, p. 48 of the Interim Reregistration Eligibility Decision [IREDE] for Oxamyl [dated October, 2000]) for a manufacturing-use product containing this active ingredient.

Table 8. Summary of Labeling Changes for Oxamyl		
Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
Formulation Instructions required on	"Only for formulation into an insecticide/acaricide/nematocide."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	<p>"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."</p> <p>"This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."</p>	
Environmental Hazards Statements	<p><b>"Environmental Hazards"</b></p> <p>"This chemical is toxic to aquatic organisms and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."</p>	Precautionary Statements under Environmental Hazards.



**Reviewer:** Byron T. Backus, Ph.D.

**Date:** March 6, 2017

**Risk Manager (EPA):** 11

The following is the Acute Toxicity Data Evaluation Record (DER) for the acute toxicity studies (MRIDs 500878-05 through -10) submitted to support the registration of EPA File Symbol 81598-RT (label declaration: 97.41% Oxamyl).

<b>1. DP BARCODE:</b> 437747				
<b>2. PC CODE:</b> 103801 (Oxamyl: 97.41%)				
<b>3. CURRENT DATE:</b> March 3, 2017				
<b>4. TEST MATERIAL:</b> From p. 14 of MRID 50087805: Oxamyl Technical, Batch No. 20160425062, described as a white powder; there is a Certificate of Analysis on p. 46 of MRID 50087805 which reports the A.I. content as 976.1 g/kg. From p. 15 of MRID 50087809 the pH of a 1% v/v aqueous solution was 7.4				
Study	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat / Palamur Biosciences, Boothpur Nandal, Mahabubnagar – 509382, Telanga State, India / Study No. 16141 / October 27, 2016 / OCSPP 870.1100: OECD 425	50087805	Up-and-down method with female Wistar rats (fasted 17-18 hrs prior to dosing). The test material was mixed with distilled water and administered at a constant dose volume of 10 mL/kg. Dosages were 1.75 mg/kg (1 rat), 2.6 mg/kg (3 rats) and 3.75 mg/kg (2 rats). There were no mortalities at 1.75 and 2.6 mg/kg; at 3.75 mg/kg both rats died within 10 minutes of dosing. Signs of toxicity: 1.75 mg/kg: none; at 2.6 mg/kg: shivering, abdominal breathing and salivation at less than 30 minutes after dosing, with recovery at 4 hours after dosing. At 3.75 mg/kg pre-death observations were shivering, abdominal breathing and salivation. All survivors gained weight from day 0 (day of dosage) to day 7, and again from day 7 to 14. Necropsy findings: no abnormalities were observed in either decedents or rats which were sacrificed at 14 days. Oral LD <sub>50</sub> = 3.17 mg/kg; 95% confidence interval 3.05-3.29 mg/kg.	I	A

Acute dermal toxicity / rat / Palamur Biosciences, Boothpur Nandal, Mahabubnagar – 509382, Telanga State, India / Study No. 16142 / October 27, 2016 OCSPP 870.1200; OECD 402	50087806	5M & 5F Wistar rats were dermally exposed for 24 hrs to 2000 mg/kg test material “moistened with a minimum volume of distilled water” applied to ~10% total body surface (previously clipped) on each rat. Each site was covered with a porous gauze dressing bandaged with non-irritating adhesive tape further covered with an elastic adhesive bandage. After 24 hrs, dressings were removed and the skin was wiped with cotton soaked with water. None of the rats died and there were no signs of systemic toxicity. There was no dermal irritation. All rats gained weight days 0-7 and 7-14. Gross necropsy: no abnormalities. Dermal LD <sub>50</sub> > 2000 mg/kg.	III	A
Acute inhalation toxicity / rat / Palamur Biosciences, Boothpur Nandal, Mahabubnagar – 509382, Telanga State, India / Study No. 16146 / October 28, 2016 / OCSPP 870.1300; OECD 403	50087807	Groups of 5M & 5F Wistar rats were exposed for 4 hrs to mean concentrations of 0.195, 0.238 or 0.285 mg/L (nominal: 10.65, 11.00 or 11.61 mg/L, respectively) test material. At 0.195 mg/L the average MMAD was 1.59 µm & the mean GSD was 2.50. At 0.238 mg/L average MMAD was 1.55 µm & mean GSD was 2.56. At 0.285 mg/L average MMAD was 1.74 µm and mean GSD was 2.48. At 0.195 mg/L 1/5M & 1/5F died; at 0.238 mg/L 3/5M & 1/5F died, and at 0.285 mg/L 5/5M & 4/5F died. Signs of toxicity: 0.195 mg/L: lethargy & lacrimation, with recovery in survivors by day 3. Deaths occurred days 1 & 2. 0.238 mg/L: At 1 hr post exposure all showed lacrimation, lethargy & tremors, with recovery in survivors by day 3. All deaths occurred on day 1. 0.285 mg/L: all had tremors from 3 <sup>rd</sup> hour of exposure, with 2M & 3F dead at 4 <sup>th</sup> hour of exposure. An additional M & F were dead at 1 hr post-exposure. On day 1 two more males were found dead. The one 0.285 mg/L survivor had tremors,	II	A

		lethargy and lacrimation up to day 6, with no signs afterwards. All rats had weight loss between day 0 and 1, but all survivors gained weight days 0-7 and 7-14. Necropsy findings in decedents included cerebral congestion of brain; congestion of lungs, congested liver, enlarged pale liver. No abnormalities were observed in survivors. Inhalation $LC_{50} = 0.23$ mg/L with 95% limits of 0.21 to 0.26 mg/L.		
Primary eye irritation / rabbit / Palamur Biosciences, Boothpur Nandal, Mahabubnagar – 509382, Telanga State, India / Study No. 16144 / October 27, 2016 / OCSPP 870.2400; OECD 405	50087808	0.1 g (100 mg) test material (as a fine dust) was instilled into the conjunctival sac of the left eye of each of 3 NZW rabbits. There was no corneal opacity, iritis, or conjunctival irritation (all eye irritation scores were zero) at 1, 24, 48 or 72 hrs. There were no signs of toxicity.	IV	A
Primary dermal irritation / rabbit / Palamur Biosciences, Boothpur Nandal, Mahabubnagar – 509382, Telanga State, India / Study No. 16143 / October 27, 2016 / OCSPP 870.2500; OECD 404	50087809	0.5 g test material (mixed “with minimum quantity of water”) was applied to one 6 cm x 6 cm clipped intact dose site on each of 3 NZW rabbits. The test site was covered with a gauze patch held in place with non-irritating tape. After 4 hrs the gauze patch was removed and the site was wiped with water. Application sites were scored at 1, 24, 48 & 72 hrs. All scores were zero (PDII = 0.0). Test material was applied over 6 cm x 6 cm; 870.2500 guidelines specify test substance should be applied to an area of $\sim 6$ cm <sup>2</sup> ( $\sim 2.5$ cm x $\sim 2.5$ cm). Study can be accepted, with assignment to toxicity category III, rather than IV.	III	A



<p>Dermal sensitization: Maximization Test, guinea pig / Palamur Biosciences, Boothpur Nandal, Mahabubnagar – 509382, Telanga State, India / Study No. 16145 / October 27, 2016 / OCSP 870.2600; OECD 406</p>	<p>50087810</p>	<p>Albino Dunkin Hartley guinea pigs were used. Based on results from pretesting, a concentration of 0.25% test item in propylene glycol was selected for intradermal induction, and 150 mg test item moistened with distilled water was selected for epidermal induction. On Day 0 the ten male guinea pigs of the induction group received 3 pairs of 0.1 mL intradermal injections: #1: 1:1 mixture (v/v) FCA/0.9% NaCl solution; #2: 0.1 mL 0.25% test item in propylene glycol; #3: 1:1 mixture of injection 1 and injection 2. Five controls were similarly injected but with no test item (vehicle only). On Day 7 a 2 cm x 4 cm piece of filter paper loaded with 150 mg test item moistened with 0.2 mL was applied to test area of males of induction group and held in contact there for 48 hrs. Negative controls were similarly exposed to distilled water. On Day 21 all 15 guinea pigs were exposed to 3 cm x 3 cm filter papers containing 100 mg test item moistened with 0.2 mL acetone, with 24 hr occlusive exposure. At about 24 and 48 hrs after removal of the patches, the site was evaluated for erythema and edema. All scores were zero, indicating the test material is a non-sensitizer. There was no mortality during the experiment. The report includes (Appendix 1) a positive control study (Maximization protocol) with 2-Mercaptobenzothiazole completed May 18, 2016 in which 5/10 induced guinea pigs and 0/5 negative controls showed a positive response.</p>	<p>Negative</p>	<p>A</p>
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n.d. = not determined; Core Grade Key: A = Acceptable, S = Supplementary, W = Waived, U = Unacceptable, D = Data Gap



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

**FEE**

**DP BARCODE No.:** D437746; **FILE SYMBOL No.:** 81598-RT; **PRODUCT NAME:** Oxamyl Technical;  
**DECISION No.:** 523784; **PC Code(s):** 103801; **ACTION CODE:** R333; **FOOD Use:** Yes

**DATE:** February 28, 2017

**SUBJECT:** Product Chemistry Review of "Oxamyl Technical"

**FROM:** Shyam Mathur, Ph. D  
Product Chemistry Team Leader  
Chemistry, Inerts & Toxicology Assessment Branch (CITAB)/RD (7505P)

*SP Mathur 03-02-17*  
*JCR*

**TO:** Carlyn Petrella / Richard Gebken, RM 11  
I-V Branch 2 / RD (7505P)

**REGISTRANT:** Rotam Limited  
**MRID Numbers:** 50087801 to 50087804 and 50087812

**INTRODUCTION:**

The registrant has submitted an application for the registration of the new technical product "Oxamyl Technical". In support of the application, the registrant has submitted a basic CSF (dated November 21, 2016) and the supporting product chemistry data with MRID Nos. 50087801 to 50087804 and 50087812. The Oxamyl technical is produced at [REDACTED]

[REDACTED] The registrant has claimed that the proposed technical is substantially similar to the registered product with Reg. No. 352-400.

CITAB has been asked to determine the acceptability of the proposed basic CSF & the supporting product chemistry data and also determine similarity to the cited product.

**SUMMARY OF FINDINGS:**

**1. Group A guidelines:**

**830.1550 (product identity & composition)**

The submitted data are acceptable. Active ingredient and process-related impurities were adequately described (MRID 50087801 and basic CSF). The nominal concentration of the active ingredient in the proposed basic CSF (97.41%, nominal) is the average derived from the 5 batch preliminary analysis. The information presented meets the data requirements for 40CFR 158.320

**830.1600 (description of materials used to produce the product)**

The product chemistry data submitted for the guideline 830.1600 (description of starting materials) are acceptable. The MSDSs of all the starting materials, and their suppliers and specifications are provided in the study with MRID 50087801. The information presented meets the data requirements for 40CFR 158.325.



**DP BARCODE No.:** D437746; **FILE SYMBOL No.:** 81598-RT; **PRODUCT NAME:** Oxamyl Technical;  
**DECISION No.:** 523784; **PC Code(s):** 103801; **ACTION CODE:** R333; **FOOD Use:** Yes

830.1620 (description of production process)

The product chemistry data submitted data for the guideline 830.1620 (description of production process) are acceptable. The oxamyl technical was [REDACTED]. The registrant has provided details of the each step of the production process with flow charts, chemical reactions pathways, and quality control measures in MRID 50087801. The information presented meets the data requirements for 40CFR 158.330.

830.1670 (discussion on the formation of impurities)

The product chemistry data submitted for the guideline 830.1670 (discussion on the formation of impurities) are acceptable. Detailed information regarding the origins of impurities was provided (MRID 50087801). Potential impurities were identified and quantified as part of the five-batch analysis (MRID 50087802). The registrant identified & quantified [REDACTED] impurities in addition to [REDACTED]. The registrant has provided mechanisms of their formation. The registrant has also discussed the toxicity of one impurity. The toxicity prediction has been submitted by using DEREK NEXUS modeling and referring the available toxicity studies. The information presented meets the data requirements for 40CFR 158.340.

830.1700 (preliminary analysis)

The five-batch analysis of the oxamyl technical was conducted to determine the contents of the active ingredient and the associated impurities as described under MRID No. 50087802. The contents of the AI was determined by HPLC-UV with internal standard quantification method and its identity was confirmed by IR, UV, <sup>1</sup>HNMR, <sup>13</sup>CNMR & LC-MS. The quantitation of significant impurities was conducted by HPLC-UV with external standard quantification method. The structure of impurities were confirmed by UV, IR & MS. The LOD & LOQ were determined for the impurities. The analytical methods were validated for linearity, accuracy and precision. The data submitted satisfy the data requirements of 40CFR§158.345.

830.1750 (certified limits)

The product chemistry data submitted for the guideline 830.1750 satisfy the data requirements of 40CFR§158.350. The registrant has proposed the nominal concentration of 97.41% for the active ingredient oxamyl which is also the product label claim nominal concentration. The proposed upper and lower certified limits for the A.I. are based on the standard certified limits, whereas the certified limits for the impurities are based on batch analysis (MRID No. 50087802).

830.1800 (enforcement analytical method)

The validated analytical method was used for the determination of the AI in Oxamyl technical. A high performance liquid chromatography (HPLC-UV) with detector operating at 240 nm was used for the determination of oxamyl. The quantitation was done by internal standard method. The method was validated for specificity, linearity, precision and accuracy. (MRID 50087803). The information presented meets the data requirements for 40 CFR §158.355.

2. Group B guidelines (physical-chemical properties):

The submitted group B product chemistry under MRID No. 50087804 satisfy the data requirements of 40CFR§158.310. The registrant has also requested waivers for few of the group B product chemistry data under MRID No. 50087812.



**DP BARCODE No.:** D437746; **FILE SYMBOL No.:** 81598-RT; **PRODUCT NAME:** Oxamyl Technical;  
**DECISION No.:** 523784; **PC Code(s):** 103801; **ACTION CODE:** R333; **FOOD Use:** Yes

## **CONCLUSIONS:**

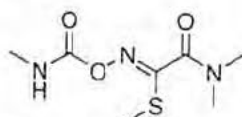
The CITAB has reviewed the proposed basic CSF and the supporting group A and group B data for Oxamyl technical and has concluded that:

1. The product chemistry data submitted for guidelines 830.1550 (product identity & composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of the production process), 830.1670 (discussion of the formation of impurities), 830.1700 (preliminary analysis) and 830.1800 (enforcement analytical method) are acceptable.
2. The proposed basic CSF (dated 11-21-2016) is acceptable. The nominal concentration of 97.41% is supported by the five batch analysis and agrees with the product label claim nominal concentration.
3. The group B product chemistry data submitted are acceptable. Based on the justifications provided, the waiver requests are acceptable.
4. One new impurity identified in oxamyl technical at the concentration of > 0.1%. CITAB Toxicologist reviewed the results of QSAR modeling software DEREK submitted for this impurity and the study was found to be acceptable. CITAB Toxicologist concluded based on the lack of significant structural alerts and small amounts in the TGAI, this impurity is unlikely to produce any significant toxicity as compared to parent compound.
5. The proposed product was determined to be not substantially similar to the registered product with Reg. No. 352-400 from the product chemistry point of view for the following reasons:
  - (i). There is significant difference in the nominal concentration of the active ingredient in the proposed & cited product (97.41% in proposed vs 42.0% in cited product).
  - (ii). Impurity profile for the two products not very similar.

**DP BARCODE No.:** D437746; **FILE SYMBOL No.:** 81598-RT; **PRODUCT NAME:** Oxamyl Technical;  
**DECISION No.:** 523784; **PC Code(s):** 103801; **ACTION CODE:** R333; **FOOD Use:** Yes

830.1550. Product identity & composition: (MRID No. 50087801)

**Common name** : Oxamyl  
**Chemical name** : *N,N*-dimethyl-2-methylcarbamoyloxyimino-2-(methylthio)acetamide (IUPAC)  
**CAS No.** : [23135-22-0]  
**Molecular formula** :  $C_7H_{13}N_3O_3S$   
**Molecular weight** : 219.3  
**Structural formula** :



**Manufacturing plant** :

**Plant site** :

\*Product ingredient source information may be entitled to confidential treatment\*

Table 1. Manufacturing and Impurity Data for "Oxamyl Technical"

GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	50087801	A	See under summary of findings
830.1600	Description of materials used to produce the product	50087801	A	See under summary of findings
830.1620	Description of production process	50087801	A	See under summary of findings
830.1670	Discussion of formation of impurities	50087801	A	See under summary of findings
830.1700	Preliminary analysis	50087802	A	See under summary of findings
830.1750	Certified limits	Basic CSF (dated 11-21-2017)	A	See under summary of findings
830.1800	Enforcement analytical method	50087803	A	See under summary of findings
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				



830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties for "Oxamyl Technical"

Table 2: Physical and Chemical Properties for "Oxamyl Technical"										
GLN	Requirement	MRID	Status	Result or Deficiency						
830.6302	Color	50087804	A	White						
830.6303	Physical state	50087804	A	Solid Powder @ 20°C						
830.6304	Odor	50087804	A	Mild characteristics odor						
830.6313 830.6317	Stability to normal and elevated temperatures, metals, and metal ions Accelerated storage stability	50087812	A	<b>Waiver request.</b> TS stable at RT & 54°C The Test Item was considered to be stable in terms of Active Ingredient content when exposed to Al, steel, Zn or Cu coupons at room temperature and at 54±2°C.						
830.6314	Oxidation/reduction; chemical incompatibility	50087812	A	<b>Waiver request.</b> Based on the chemical structure the TS does not contain either an oxidizing or reducing functional group						
830.6315	Flammability	50087812	A	<b>Waiver request.</b> TS is solid material with MP of 211°F						
830.6316	Explosibility	50087812	A	<b>Waiver request.</b> TS does not have potential to explode						
830.6317	Accelerated storage stability	50087804	A	The Test Item is stable for 14 Days at room Temperature and at 54±2°C.						
830.6319	Miscibility	50087812	NA	Not applicable to solid products						
830.6320	Accelerated Corrosion characteristics	50087804	A	No corrosion of the commercial packages after storage for 14 days at room temperature and 54±2°C						
830.7000	pH	50087804	A	7.69 at 20°C (1% w/v dilution in water)						
830.7050	UV/Visible absorption	50087812	A	<b>Waiver request</b> Neutral solution-80.1 (L/mol.cm) at 290 nm Acidic solution - 60.1 (L/mol.cm) at 290 nm Basic solution- 1154 (L/mol.cm) at 290 nm						
830.7100	Viscosity	50087812	NA	TS is a solid						
830.7200	Melting point	50087804	A	96.4°C to 99.6°C						
830.7220	Boiling point	50087804	NA							
830.7300	Density	50087804	A	0.97521 g/ml @ 20°C						
830.7370	Dissociation constants in water (DC)	50087804	A	pK <sub>b</sub> = 6.5 @ 20°C						
830.7550	Partition coefficient	50087804	A	<table><tr><td>Distilled water (pH 6.28)</td><td>Log P<sub>ow</sub> = -0.49 at 25°C</td></tr><tr><td>pH 5.0 buffer</td><td>Log P<sub>ow</sub> = -0.46 at 25°C</td></tr><tr><td>pH 7.0 buffer</td><td>Log P<sub>ow</sub> = -0.47 at 25°C</td></tr></table>	Distilled water (pH 6.28)	Log P <sub>ow</sub> = -0.49 at 25°C	pH 5.0 buffer	Log P <sub>ow</sub> = -0.46 at 25°C	pH 7.0 buffer	Log P <sub>ow</sub> = -0.47 at 25°C
Distilled water (pH 6.28)	Log P <sub>ow</sub> = -0.49 at 25°C									
pH 5.0 buffer	Log P <sub>ow</sub> = -0.46 at 25°C									
pH 7.0 buffer	Log P <sub>ow</sub> = -0.47 at 25°C									
830.7840	Water solubility	50087804	A	D.Water = 226.27 g/L (pH 6.28) @ 20°C pH 5 buffer = 217.25 g/L @ 20°C pH 7 buffer = 206.63 g/L @ 20°C						
830.7950	Vapor pressure	50087804	A	5.01 x 10 <sup>-5</sup> Pa @20°C						
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required); W = waivers										

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress;  
 U = Up-grade (additional information required); W = waivers

DP BARCODE No.: D4377; FILE SYMBOL No.: 81598-RT; PRODUCT NAME: Oxamyl Technical;  
DECISION No.: 523784; PC Code(s): 103801; ACTION CODE: R333; FOOD Use: Yes

Solubility in organic solvents (MRID No. 50087812)

Solvent	Solubility mg/l 20°C
n-heptane	10,500
Methanol	250,000
Acetone	250,000
Xylene	42,300

830.1800 (enforcement analytical method)  
 (MRID No. 50087803)

The content of the active ingredient oxamyl was determined by Test Method CIPAC (M) 342/TC/M/-: Oxamyl Technical. The analytical method used HPLC-UV (240 nm) with internal standard quantification. The method was validated for linearity, accuracy & precision. Summary of Method Validation is provided in the following table.

Parameters		Results
Specificity		No peak was observed interfering with the peak of
Linearity	Linearity range	24.74 mg to 50.51 mg in 25 ml solution
	Slope	0.0186
	Correlation	0.9997
	RSD	0.06%
System precision	Horwitz	3.57%
	RSD	0.20%
Assay precision	Horwitz	1.34%
	RSD	

#### Equipment and Parameters

**HPLC:** with G1311 A pump System with DAD

**Column:** XDB-C<sub>8</sub> (150 mm x 4.6 mm; 5 µm)

**Mobile Phase:** Milli-Q Water (adjusted to pH =2.7 with H<sub>3</sub>PO<sub>3</sub>) + Acetonitrile [90% + 10% (v/v)];

**Flow Rate:** 2.0 ml/min

**Detector:** UV operating at 240 nm

**Temperature:** 40°C

**Injection volume:** 5 µL

**Retention time for the AI:** about 3.0 minutes; Acetanilide (IS) = about 6.3 minute

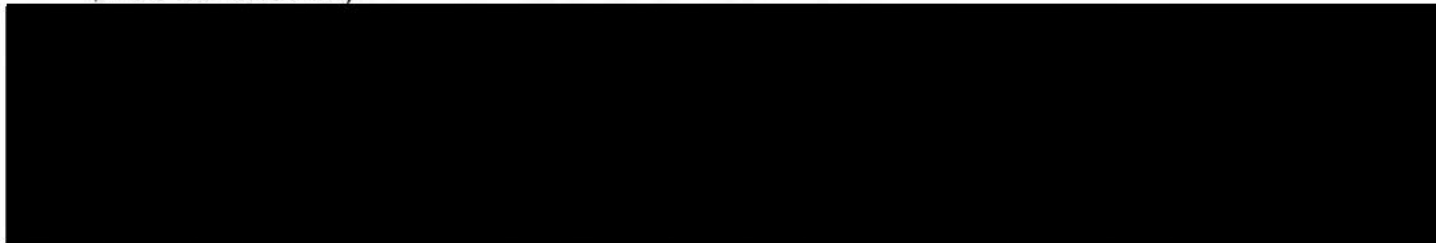
See the details of the method under MRID No. 50087803.



DP BARCODE No.: D4377 FILE SYMBOL No.: 81598-RT; PRODUCT NAME: Oxamyl Technical;  
DECISION No.: 523784; PC Code(s): 103801; ACTION CODE: R333; FOOD Use: Yes

CONFIDENTIAL APPENDIX

830.1600 (description of materials used to produce the product)  
(MRID No. 50087801)

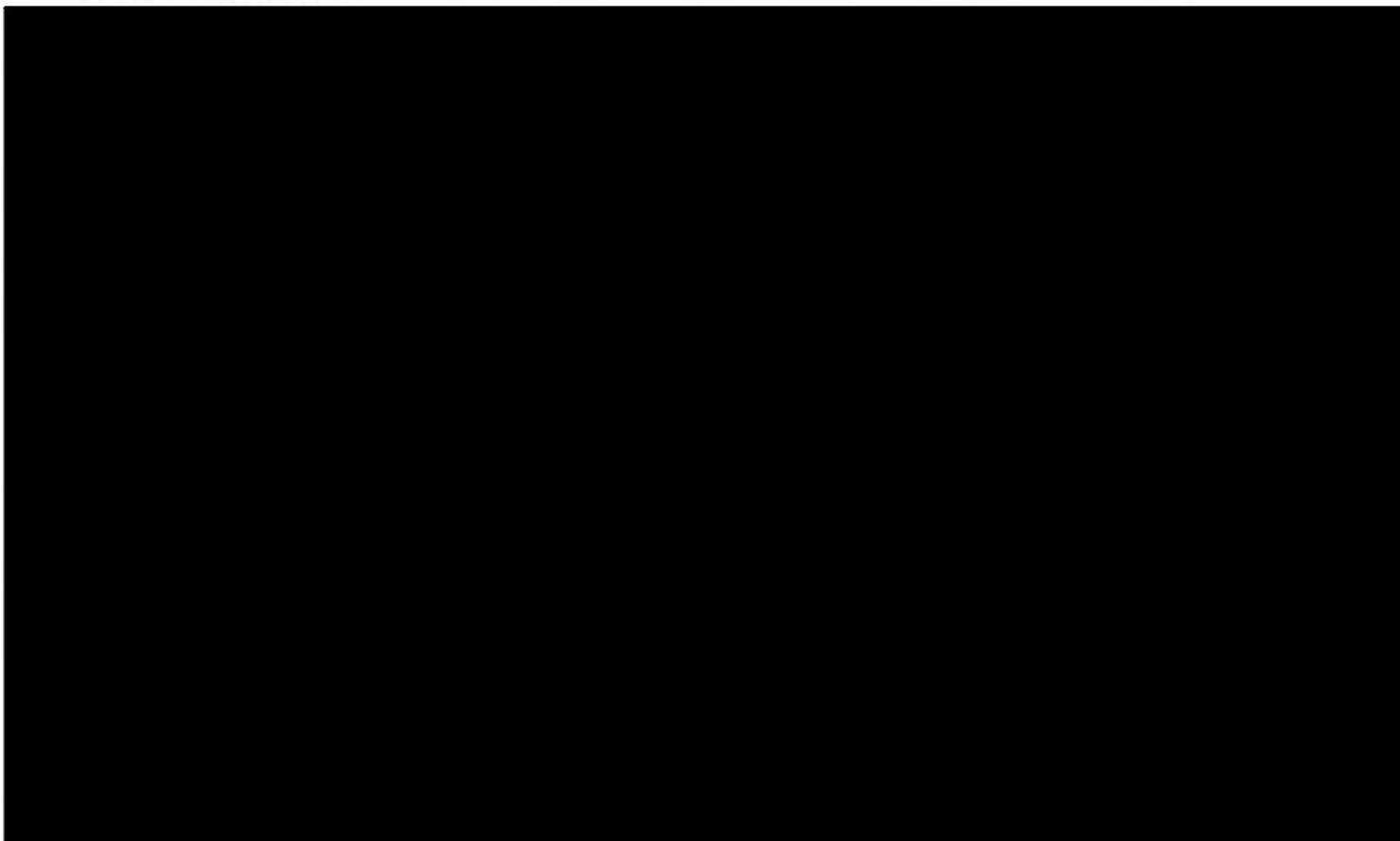


830.1620 (description of production process)  
(MRID provided No. 50087801)

**Manufacturing facility**



**Production process:**



\*Manufacturing process information may be entitled to confidential treatment\*

\*Product ingredient source information may be entitled to confidential treatment\*





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D437746; FILE SYMBOL No.: 81598-RT (screen); PRODUCT NAME: Oxamyl  
Technical; DECISION No.: 523784; PC Code(s): 103801; ACTION CODE: R333; FOOD Use: Yes

DATE OUT: February 13, 2017

SUBJECT: 45/90 day screen results for technical product: "Oxamyl Technical"

FROM: Shyam Mathur, Chemistry Team Leader, CITAB / RD (7505P)

TO: Carlyn Petrella / Richard Gebken, RM 11, I-V Branch 2 / RD (7505P)

Company Name: Rotam Limited  
Active Ingredient(s): Oxamyl (97.41%)  
MRID No(s): 50087801 to 50087804 and 50087812

CONCLUSION:

**Deficiencies: No**

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc)

**Group A:** All required data submitted

**Group B:** All required data submitted,

**CSF:** Proposed Basic CSF (dated 11-21-2016) submitted

**DRAFT PRODUCT LABEL:** Submitted

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to the author of this report the corrected deficiencies in response to 10 day letter. The corrected deficiencies will be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

**DP BARCODE No.:** D437746; **FILE SYMBOL No.:** 81598-RT (screen); **PRODUCT NAME:** Oxamyl Technical; **DECISION No.:** 523784; **PC Code(s):** 103801; **ACTION CODE:** R333; **FOOD Use:** Yes

**DATE OUT:** February 13, 2017

**SUBJECT:** 45/90 day screen results for technical product: "Oxamyl Technical"

**FROM:** Shyam Mathur, Chemistry Team Leader, CITAB / RD (7505P)

**TO:** Carlyn Petrella / Richard Gebken, RM 11, I-V Branch 2 / RD (7505P)

**Company Name:** Rotam Limited

**Active Ingredient(s):** Oxamyl (97.41%)

**MRID No(s):** 50087801 to 50087804 and 50087812

**CONCLUSION:**

**Deficiencies:** No

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc)

**Group A:** All required data submitted

**Group B:** All required data submitted,

**CSF:** Proposed Basic CSF (dated 11-21-2016) submitted

**DRAFT PRODUCT LABEL:** Submitted

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to the author of this report the corrected deficiencies in response to 10 day letter. The corrected deficiencies will be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.



## Walsh, Michael

---

**From:** Petrella, Carlyn  
**Sent:** Thursday, March 16, 2017 2:13 PM  
**To:** Walsh, Michael  
**Subject:** FYI FW: Oxamyl

Hi Mike.

DCI is still open for Oxamyl, so will be a conditional registration.

Thanks,

Carlyn

**From:** Piansay, Maria  
**Sent:** Thursday, March 16, 2017 2:00 PM  
**To:** Petrella, Carlyn <Petrella.Carlyn@epa.gov>  
**Subject:** RE: Oxamyl

Hi Carlyn - sorry it took a while to respond. I told you over the phone this morning that I would check on the status of the DCI and what I found out is there is one data gap that the registrant is still trying to fulfill (a pollinator study), therefore, I can tell you for sure that the DCI has not been closed for oxamyl.

Thank you and if you have more questions, let me know.  
Maria

**From:** Petrella, Carlyn  
**Sent:** Wednesday, March 15, 2017 10:01 AM  
**To:** Piansay, Maria <[Piansay.Maria@epa.gov](mailto:Piansay.Maria@epa.gov)>  
**Cc:** Walsh, Michael <[Walsh.Michael@epa.gov](mailto:Walsh.Michael@epa.gov)>  
**Subject:** Oxamyl

Hi Maria.

Just a few things regarding oxamyl.

I wanted you to know that RD recently approved a new source of oxamyl for DuPont. IVB2 also has five new product applications pending for oxamyl products. Four of the actions are from Rotam and one is from Orion. They have various PRIA due dates, but RD is expediting a few of the actions to make oxamyl available to growers as soon as possible.

I also wanted to know if there are any open DCIs for oxamyl. I think the DCI is closed as closed as of 2013, but I just wanted to be sure since we will use the information to determine the type of registration - - conditional or unconditional.

Please let me know as soon as possible about the DCIs.

Many thanks.

Carlyn

PRD  
DCI STATUS



United States  
**Environmental Protection Agency**  
 Washington, DC 20460



Registration

OPP Identifier Number



Amendment



Other

### Application for Pesticide - Section I

1. Company/Product Number 81598-XX	2. EPA Product Manager Richard Gebken	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Rotam Limited / Oxamyl Technical	PM# 10	
5. Name and Address of Applicant (Include Zip Code) Rotam Limited c/o Wagner Regulatory Associates, Inc. P.O. Box 640, 7217 Lancaster Pike, Suite A Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No.: 352-400 Product Name: DuPont Oxamyl Technical 42 Insecticide/Nematicide	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

**PRIA Category R333 – Primary Submission linked to three additional secondary submissions for new product registrations (Oxamyl 42% MUP 81598-XX; Oxamyl 42% SL 83100-XX; and Oxamyl 24% SL 83100-XX) submitted concurrently with this application.**

### Section - III

#### 1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) HDPE lined bags
* Certification must be submitted		If "Yes" No. per Unit Packaging wt. container	If "Yes" No. per Package wt. container

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container bulk	5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product
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6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____
--	--------------------------------------

### Section - IV

#### 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name James Wagner	Title Agent for Rotam Limited	Telephone No. (Include Area Code) (302) 635-7290 or jmw@wagnerreg.com
----------------------	----------------------------------	--

#### Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Agent for Rotam Limited	6. Date Application Received  (Stamped)
4. Typed Name James Wagner	5. Date November 21, 2016	



Submitted Electronically

November 21, 2016

Document Processing Desk (**REGFEE**)  
ATTN: Richard Gebken, PM No. 10  
Registration Division  
U.S. Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202-4501

**WRA**

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

Dear Mr. Gebken,

**Subject: Oxamyl Technical - Application to register a new technical product containing the currently registered active ingredient Oxamyl - PRIA R333**

Wagner Regulatory Associates, Inc., as agent for Rotam Limited (EPA Co. Number 81598), is requesting registration of the product "Oxamyl Technical".

Please note that this submission is a PRIA Primary Application that is linked to three Secondary Applications (R333.2). All four applications are being submitted simultaneously. The Secondary Applications are:

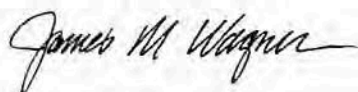
1. Oxamyl 42% MUP
2. Oxamyl 42% SL
3. Oxamyl 24% SL

In support of this request, the following documents are attached:

- Letter from Rotam Limited appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Confidential Statement of Formula (8570-4)
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (internal and public copies) (8570-35)
- Draft labeling
- Certification with Respect to Label Integrity
- Data transmittal document
- Product chemistry and acute toxicity data as listed in the transmittal document
- A copy of the receipt confirming payment of the required registration fee for R333 - \$19,838.

Please do not hesitate to contact me should you have any questions regarding this submission. Thank you in advance.

Respectfully submitted,



James Wagner  
Agent for Rotam Limited  
Tel: 302-635-7290  
Email: [jmw@wagnerreg.com](mailto:jmw@wagnerreg.com)

Enclosures

**DATA TRANSMITTAL DOCUMENT****1. Name and Address of Submitter**

Rotam Limited  
 c/o Wagner Regulatory Associates  
 PO Box 640  
 Hockessin, DE 19707

**2. Regulatory Action In Support Of Which This Package Is Submitted**

Application for Registration  
**Oxamyl Technical**

**3. Transmittal Date**

November 21, 2016

**4. List of Submitted Studies**

50087801	Oxamyl Technical - Product Identity and Composition, Description of Materials, Manufacturing Process, Formation and Toxicity of Impurities, OPPTS: 830.1600, 830.1620, 830.1670
50087802	Analysis Of Five Representative Production Batches Of Oxamyl Technical Grade Active Ingredient (TGAI) To Identify And Quantify Oxamyl And Its Associate Impurities, Study No. 1829, OPPTS: 830.1700, 830.1800
50087803	Study On The Method Validation Of Oxamyl Technical, Study No. 1844, OPPTS: 830.1800
50087804	Study On The Physico-Chemical Properties Of Oxamyl Technical, Study No. 1845, OPPTS: 830.6302, 830.6303, 830.6304, 830.6317, 830.6320, 830.7000, 830.7200, 830.7300, 830.7370, 830.7550, 830.7840, 830.7950
50087805	Oxamyl Technical: Acute Oral Toxicity Study (Up-and-Down Procedure) in female Wistar rats, Study No. 16141, OPPTS: 870.100
50087806	Oxamyl Technical: Acute Dermal Toxicity Study in Wistar Rats. Study No. 16142, OPPTS: 870.1200
50087807	Oxamyl Technical: Acute Inhalation Toxicity Study in Wistar Rats, Study No. 16146, OPPTS: 870.1300
50087808	Oxamyl Technical: Acute Eye Irritation / Corrosion Study in New Zealand White Rabbits, Study No. 16144, OPPTS: 870.2400
50087809	Oxamyl Technical : Acute Dermal Irritation / Corrosion Study in New Zealand White Rabbits, Study No. 16143, OPPTS: 870.250
50087810	Oxamyl Technical: Skin Sensitization Study (Magnusson and Kligman Test) in Guinea Pigs, Study No. 16145, OPPTS: 870.2600
50087811	In Silico Toxicity Assessment for OXYL01 Impurity Using DEREK NEXUS, OPPTS: 830.1670, 830.7840
50087812	Oxamyl Technical: Certified Limits, Public Literature Citations and Request for Waiver for Certain Physical Chemical Properties Data Requirements, OPPTS: 830.1750, 830.6313, 830.6314; 830.6315, 830.6316, 830.6321, 830.7050, 830.7840

**Company Official:**

James Wagner  
 Authorized Agent

  
 Signature

**Company Name:** Rotam Limited

**Company Contact:** James Wagner  
 Authorized Agent

(302) 635-7290  
 Phone



U.S. Environmental Protection Agency  
Office of Pesticide Programs (7505P)  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Dear Sir or Madam:

This letter serves as notification that **ROTAM LIMITED** (Firm Number: 81598) has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as its Agent regarding all pesticide registration matters the company may have with the U.S. Environmental Protection Agency (EPA).

ROTAM LIMITED hereby authorizes EPA to contact any of the following individuals within WRA, Inc. on behalf of the company:

James M. Wagner  
Managing Director  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7290  
Fax: (302) 635-7295  
Email: [james@wagnerreg.com](mailto:james@wagnerreg.com)

Ceryl R. Wagner  
President  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7289  
Fax: (302) 635-7295  
Email: Ceryl@wagnerreg.com

Kt Woodall  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7283  
Fax: (302) 635-7295  
Email: [Ktwoodall@wagnerreg.com](mailto:Ktwoodall@wagnerreg.com)

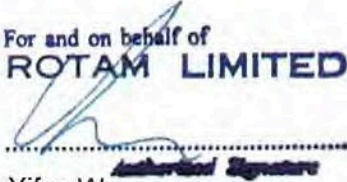
Carrie Nolan  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302)635-7632  
Fax: (302) 635-7295  
Email: [Carrie@wagnerreg.com](mailto:Carrie@wagnerreg.com)

Barbarette Young-Henry  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7279  
Fax: (302) 635-7295  
Email: [Barbarette@wagnerreg.com](mailto:Barbarette@wagnerreg.com)

Authorization to contact these staff members within WRA, Inc remains in effect until such time that **ROTAM LIMITED** provides notification in writing of any changes.

Respectfully submitted,

For and on behalf of  
**ROTAM LIMITED**

A handwritten signature in blue ink, appearing to read "Yifan Wu", written over a dotted line.

Yifan Wu  
Head of Research, Development and Registration Division  
Tel: 86-512-5790 3076  
Fax: 86-512-5771 8692  
Email: yifanwu@rotam.com

cc: WRA, Inc.



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1200 Pennsylvania Avenue, N.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

## Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number

Rotam Limited, c/o Wagner Regulatory Associates, P.O. Box 640, Hockessin, DE 19707

EPA Registration Number/File Symbol

81598-XX

Active Ingredient(s) and/or representative test compound(s)

Oxamyl

Date

November 21, 2016

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)

Terrestrial Food and Non-Food

Product Name

Oxamyl Technical

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).



I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

## SECTION I: METHOD OF DATA SUPPORT (Check one method only)



I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

## SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]



I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

## SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

*James M. Wagner*

Date

11/21/2016

Typed or Printed Name and Title

James M. Wagner, Agent





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: November 21, 2016

EPA Reg No./ File Symbol: 81598-XX

Page 1 of 3

Applicant's/Registrant's Name and Address: Rotam Limited  
c/o Wagner Regulatory Associates Inc.  
P.O. Box 640, 7217 Lancaster Pike, Suite A  
Hockessin, DE 19707

Product:

Oxamyl Technical

Ingredient: OXAMYL

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>PRODUCT SPECIFIC</b>					
830.1550, 830.1600,	Product identity, composition/Description of materials Used to Produce the Product	50087801	Rotam Limited	Own	
830.1620	Description of Production Process	50087801	Rotam Limited	Own	
830.1650	Description of Formulation Process	50087801	Rotam Limited	Own	
830.1670	Discussion of Formation of Impurities	50087801, 50087811	Rotam Limited	Own	
830.1700	Preliminary Analysis	50087802	Rotam Limited	Own	
830.1750	Certification of Limits	50087812	Rotam Limited	Own	
830.1800	Enforcement Analytical Method	50087803	Rotam Limited	Own	
830.6302	Color	50087804	Rotam Limited	Own	
830.6303	Physical State	50087804	Rotam Limited	Own	
830.6304	Odor	50087804	Rotam Limited	Own	
830.6313	Stability to Normal & Elevated Temperatures	50087812	Rotam Limited	Own	
830.6314	Oxidation/Reduction	50087812	Rotam Limited	Own	
830.6315	Flammability	50087812	Rotam Limited	Own	
830.6316	Explosibility	50087812	Rotam Limited	Own	
830.6317	Storage Stability	50087812	Rotam Limited	Own	
830.6319	Miscibility	50087804	Rotam Limited	Own	
830.6320	Corrosion Characteristics	50087812	Rotam Limited	Own	
830.6321	Dielectric breakdown voltage	50087812	Rotam Limited	Own	
830.7000	pH	50087804	Rotam Limited	Own	
830.7050	UV/Visible Light Absorption	50087812	Rotam Limited	Own	
830.7100	Viscosity	50087812	Rotam Limited	Own	

Signature

Name and Title

James Wagner, Agent for Rotam Limited

Date

11/21/2016

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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401 M Street, S.W.

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## DATA MATRIX

Date: November 21, 2016

EPA Reg No./ File Symbol: 81598-XX

Page 2 of 3

Applicant's/Registrant's Name and Address: Rotam Limited  
c/o Wagner Regulatory Associates Inc.  
P.O. Box 640, 7217 Lancaster Pike, Suite A  
Hockessin, DE 19707

Product:

Oxamyl Technical

Ingredient: OXAMYL

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7200	Melting Point	50087804	Rotam Limited	Own	
830.7220	Boiling Point	50087812	Rotam Limited	Own	
830.7300	Relative Density	50087804	Rotam Limited	Own	
830.7370	Dissociation Constants in Water	50087804	Rotam Limited	Own	
830.7520	Particle Size	50087812	Rotam Limited	Own	
830.7550	Octanol/Water Partition Coefficient	50087804	Rotam Limited	Own	
830.7840	Solubility in Water/Organic Solvents	50087804, 50087811	Rotam Limited	Own	
830.7950	Vapor Pressure	50087804	Rotam Limited	Own	
870.1100	Acute Oral Toxicity	50087805	Rotam Limited	Own	
870.1200	Acute Dermal Toxicity	50087806	Rotam Limited	Own	
870.1300	Acute Inhalation Toxicity	50087807	Rotam Limited	Own	
870.2400	Primary Eye Irritation	50087808	Rotam Limited	Own	
870.2500	Primary Dermal Irritation	50087809	Rotam Limited	Own	
870.2600	Dermal Sensitization	50087810	Rotam Limited	Own	

Signature

Name and Title  
James Wagner, Agent for Rotam Limited

Date  
11/21/2016

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.

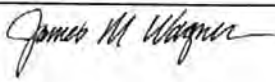
WASHINGTON, D.C. 20460

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## DATA MATRIX

Date: November 21, 2016	EPA Reg No./ File Symbol: 81598-XX	Page 3 of 3
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640, 7217 Lancaster Pike, Suite A Hockessin, DE 19707	Product: <b>Oxamyl Technical</b>	
Ingredient: <b>OXAMYL</b>		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
GENERIC DATA			SYNGENTA CROP PROTECTION, LLC Greensboro, NC  BAYER CROPSCIENCE LP Research Triangle, NC  E. I. DU PONT DE NEMOURS AND COMPANY (S300/419) Wilmington, DE  VALENT U.S.A. CORPORATION Walnut Creek, CA  SPRAY DRIFT TASK FORCE AGRICULTURAL REENTRY TASK FORCE FIFRA ENDANGERED SPECIES TASK FORCE, L.L.C. AGRICULTURAL HANDLER EXPOSURE TASK FORCE Washington DC  REINTJES MARINE SURFACE TECHNOLOGIES, LLC, Great Falls, VA	PAY	

Signature 	Name and Title James Wagner, Agent for Rotam Limited	Date 11/21/2016
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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

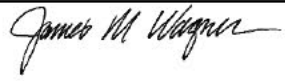
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: November 21, 2016	EPA Reg No./ File Symbol: 81598-XX	Page 1 of 3
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640, 7217 Lancaster Pike, Suite A Hockessin, DE 19707	Product: <b>Oxamyl Technical</b>	
Ingredient: <b>OXAMYL</b>		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	
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			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	

Signature 	Name and Title James Wagner, Agent for Rotam Limited	Date 11/21/2016
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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

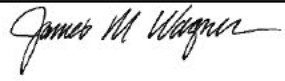
WASHINGTON, D.C. 20460

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Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640, 7217 Lancaster Pike, Suite A Hockessin, DE 19707	Product: <b>Oxamyl Technical</b>	
Ingredient: <b>OXAMYL</b>		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	

Signature 	Name and Title James Wagner, Agent for Rotam Limited	Date 11/21/2016
		68





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

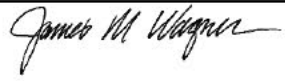
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Signature 	Name and Title James Wagner, Agent for Rotam Limited	Date 11/21/2016  69
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## Walsh, Michael

---

**From:** James Wagner <jmw@wagnerreg.com>  
**Sent:** Tuesday, February 07, 2017 3:06 PM  
**To:** Petrella, Carlyn; Walsh, Michael  
**Cc:** Anna Armstrong  
**Subject:** RE: Oxamyl Technical & MUP Product Data Compensation. Response needed.  
**Attachments:** Rotam Oxamyl Tech and 42% MUP OTPs 30Nov2017.pdf

Dear Carlyn and Mike,

The requested documents are attached.

Best regards,

Jim Wagner  
Regulatory Consultant  
Tel: (302) 635-7290  
Mobile: (302) 530-5745

**From:** Petrella, Carlyn [mailto:Petrella.Carlyn@epa.gov]  
**Sent:** Tuesday, February 07, 2017 1:57 PM  
**To:** Anna Armstrong <Anna@wagnerreg.com>; James Wagner <jmw@wagnerreg.com>  
**Cc:** Walsh, Michael <Walsh.Michael@epa.gov>  
**Subject:** Oxamyl Technical & MUP Product Data Compensation. Response needed.

Dear Mr. Wagner and Ms. Armstrong:

For your November 21, 2016 submissions for new product applications 81598-RA (Rotam Oxamyl 42% MUP) and 81598-RT (Rotam Oxamyl Technical), please provide copies of all offers to pay compensation for the data cited in your applications. Please also be sure to provide evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA.

Please submit the documents within the next 5 business days.

Thank you for your prompt attention to this matter.

Mike



JACKET  
81598-RA

**WRA**

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Reintjes Marine Surface Technologies  
Walter G. Talarek, PC  
1008 Riva Ridge Drive  
Great Falls, VA 22066

**Re: Offer to Pay**

Dear Sir or Madam:

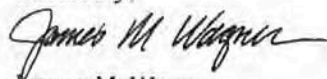
Rotam Limited is submitting a registration application to the U.S. Environmental Protection Agency ("EPA") for the product "Oxamyl Technical" containing Oxamyl as the active ingredient. This application relies on the cite-all method of support to satisfy generic data requirements. Your company is listed on the most recent EPA "Data Submitters List" for this active ingredient.

In accordance with the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") Section 3(c)(1)(F), Rotam Limited hereby offers to pay compensation after the approval of this application, to the extent required by Section 3(c)(1)(F) for specific and valid data for which your company is identified by the EPA as an original data submitter and on which this application relies. Rotam Limited offers to begin negotiations to determine which data are subject to the compensation regulations of FIFRA and the amount and terms of the compensation, if any, to be paid for any such data.

Further, if there are any studies that are in progress and that you are required to submit to EPA in response to a pending data call-in for Oxamyl, Rotam Limited hereby offers to jointly develop or share in the cost of development of such studies.

For each study for which EPA which you seek compensation, you propose.

Sincerely,

  
James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com

**SENDER: COMPLETE THIS SECTION**

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Reintjes Marine Surface Technologies  
Walter G. Talarek, PC  
1008 Riva Ridge Drive  
Great Falls, VA 22066  
(Rotam Oxamyl 42% MUP) +Tech



9590 9402 2267 6225 8969 59

2. Article Number (Transfer from service label)

7016 2140 0001 1479 6142

**COMPLETE THIS SECTION ON DELIVERY**

A. Signature

X

 ☐ Agent  
☒ Addressee

B. Received by (Printed Name)

C. Date of Delivery

12-2-16

D. Is delivery address different from item 1? ☐ Yes  
If YES, enter delivery address below: ☐ No

3. Service Type

- ☐ Adult Signature
- ☐ Adult Signature Restricted Delivery
- ☐ Certified Mail®
- ☐ Certified Mail Restricted Delivery
- ☐ Collect on Delivery
- ☐ Collect on Delivery Restricted Delivery
- ☐ Priority Mail Express®
- ☐ Registered Mail™
- ☐ Registered Mail Restricted Delivery
- ☐ Return Receipt for Merchandise
- ☐ Signature Confirmation™
- ☐ Signature Confirmation Restricted Delivery

**WRA**

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Reintjes Marine Surface Technologies  
Walter G. Talarek, PC  
1008 Riva Ridge Drive  
Great Falls, VA 22066

**Re: Offer to Pay**

Dear Sir or Madam:

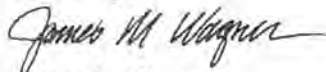
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Further, if there are any studies that are in progress and that you are required to submit to EPA in response to a pending data call-in for Oxamyl, Rotam Limited hereby offers to jointly develop or share in the cost of developing such studies to the extent required by FIFRA Section 3(c)(2)(B).

For each study for which EPA considers your company to be an original data submitter and for which you seek compensation, please identify the data items and any terms of compensation that you propose.

Sincerely,



James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com



# WRA

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

E.I. Du Pont de Nemours and Company  
Manager, US Registration, DuPont  
Chestnut Run Plaza, 974 Centre Road  
Wilmington, DE 19805

**Re: Offer to Pay**

Dear Sir or Madam:

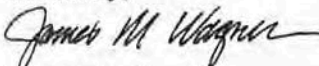
Rotam Limited is submitting a registration application to the U.S. Environmental Protection Agency ("EPA") for the product "Oxamyl Technical" containing Oxamyl as the active ingredient. This application relies on the cite-all method of support to satisfy generic data requirements. Your company is listed on the most recent EPA "Data Submitters List" for this active ingredient.

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For each study for which E  
which you seek compensati  
you propose.

Sincerely,

  
James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.co

## SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

E.I. Du Pont de Nemours & Company  
Manager, US Registration, DuPont  
Chestnut Run Plaza, 974 Centre Road  
Wilmington, DE 19805  
(Rotam Oxamyl 42% MUP) & Tech



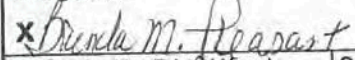
9590 9402 2267 6225 8969 66

2. Article Number (Transfer from service label)

7016 2140 0001 1479 6128

## COMPLETE THIS SECTION ON DELIVERY

A. Signature



☒ Agent

☐ Addressee

B. Received by (Printed Name)

Brenda M. Pleasant

C. Date of Delivery

12/02/16

D. Is delivery address different from item 1? ☐ Yes  
If YES, enter delivery address below: ☐ No

3. Service Type

☐ Adult Signature

☐ Adult Signature Restricted Delivery

☐ Certified Mail®

☐ Certified Mail Restricted Delivery

☐ Collect on Delivery

☐ Collect on Delivery Restricted Delivery

☐ Registered Mail

☐ Registered Mail Restricted Delivery

☐ Return Receipt for Merchandise

☐ Signature Confirmation™

☐ Signature Confirmation Restricted Delivery

☐ Priority Mail Express®

☐ Registered Mail™

☐ Registered Mail Restricted Delivery

☐ Return Receipt for Merchandise

☐ Signature Confirmation™

☐ Signature Confirmation Restricted Delivery

**WRA**

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

E.I. Du Pont de Nemours and Company  
Manager, US Registration, DuPont  
Chestnut Run Plaza, 974 Centre Road  
Wilmington, DE 19805

**Re: Offer to Pay**

Dear Sir or Madam:

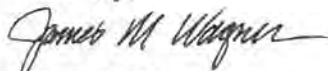
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In accordance with the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") Section 3(c)(1)(F), Rotam Limited hereby offers to pay compensation after the approval of this application, to the extent required by Section 3(c)(1)(F) for specific and valid data for which your company is identified by the EPA as an original data submitter and on which this application relies. Rotam Limited offers to begin negotiations to determine which data are subject to the compensation regulations of FIFRA and the amount and terms of the compensation, if any, to be paid for any such data.

Further, if there are any studies that are in progress and that you are required to submit to EPA in response to a pending data call-in for Oxamyl, Rotam Limited hereby offers to jointly develop or share in the cost of developing such studies to the extent required by FIFRA Section 3(c)(2)(B).

For each study for which EPA considers your company to be an original data submitter and for which you seek compensation, please identify the data items and any terms of compensation that you propose.

Sincerely,



James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com



# WRA

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Agricultural Handler Exposure Task Force  
Johnson Management & Consulting, LLC  
P.O. Box 509, 1720 Prospect Drive  
Macon, MO 63552

**Re: Offer to Pay**

Dear Sir or Madam:

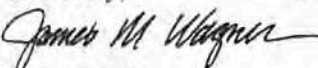
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In accordance with the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") Section 3(c)(1)(F), Rotam Limited hereby offers to pay compensation after the approval of this application, to the extent required by Section 3(c)(1)(F) for specific and valid data for which your company is identified by the EPA as an original data submitter and on which this application relies. Rotam Limited offers to begin negotiations to determine which data are subject to the compensation regulations of FIFRA and the amount and terms of the compensation, if any, to be paid for any such data.

Further, if there are any studies that are in progress and that you are required to submit to EPA in response to a pending data call-in for Oxamyl, Rotam Limited hereby offers to jointly develop or share in the cost of development of such studies. If you agree, please sign and return this card to EPA or share in the cost of development of such studies. (3(c)(2)(B)).

For each study for which EPA requires data, which you seek compensation for, please indicate the study number and the study description you propose.

Sincerely,

  
James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com

**SENDER: COMPLETE THIS SECTION**

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Agricultural Handler Exp Task Force  
Johnson Mgmt & Consulting, LLC  
P.O. Box 509, 1720 Prospect Drive  
Macon, MO 63552

(Rotam Oxamyl 42% MUP) + Tech



9590 9402 2267 6225 8969 80

2. Article Number (Transfer from service label)

7016 2140 0001 1479 6098

**COMPLETE THIS SECTION ON DELIVERY**

A. Signature



☐ Agent  
☒ Addressee

B. Received by (Printed Name)

Rose Anna Johnson

C. Date of Delivery

D. Is delivery address different from item 1? ☐ Yes  
If YES, enter delivery address below: ☐ No

3. Service Type

- ☐ Adult Signature
- ☐ Adult Signature Restricted Delivery
- ☐ Certified Mail®
- ☐ Certified Mail Restricted Delivery
- ☐ Collect on Delivery
- ☐ Collect on Delivery Restricted Delivery
- ☐ Mail Restricted Delivery (JM)

- ☐ Priority Mail Express®
- ☐ Registered Mail™
- ☐ Registered Mail Restricted Delivery
- ☐ Return Receipt for Merchandise
- ☐ Signature Confirmation™
- ☐ Signature Confirmation Restricted Delivery

# WRA

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Agricultural Handler Exposure Task Force  
Johnson Management & Consulting, LLC  
P.O. Box 509, 1720 Prospect Drive  
Macon, MO 63552

**Re: Offer to Pay**

Dear Sir or Madam:

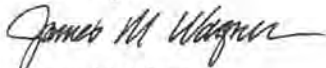
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For each study for which EPA considers your company to be an original data submitter and for which you seek compensation, please identify the data items and any terms of compensation that you propose.

Sincerely,



James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

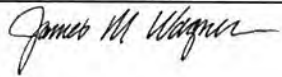
Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
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			Rotam Limited	Own	

Signature 	Name and Title James Wagner, Agent for Rotam Limited	Date 11/21/2016 77
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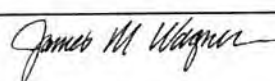
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

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			Rotam Limited	Own	
			Rotam Limited	Own	
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			Rotam Limited	Own	
			Rotam Limited	Own	

Signature 	Name and Title James Wagner, Agent for Rotam Limited	Date 11/21/2016
--	---	--------------------



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

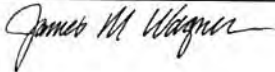
Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

**DATA MATRIX**

Date: November 21, 2016	EPA Reg No./ File Symbol: 81598-XX	Page 3 of 3
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640, 7217 Lancaster Pike, Suite A Hockessin, DE 19707	Product: <b>Oxamyl Technical</b>	
Ingredient: <b>OXAMYL</b>		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			SYNGENTA CROP PROTECTION, LLC Greensboro, NC  BAYER CROPSCIENCE LP Research Triangle, NC  E. I. DU PONT DE NEMOURS AND COMPANY (S300/419) Wilmington, DE  VALENT U.S.A. CORPORATION Walnut Creek, CA  SPRAY DRIFT TASK FORCE AGRICULTURAL REENTRY TASK FORCE FIFRA ENDANGERED SPECIES TASK FORCE, L.L.C. AGRICULTURAL HANDLER EXPOSURE TASK FORCE Washington DC  REINTJES MARINE SURFACE TECHNOLOGIES, LLC, Great Falls, VA	PAY	

Signature 	Name and Title James Wagner, Agent for Rotam Limited	Date 11/21/2016 79
--	---	--------------------------





# WRA

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Bayer Cropscience LP  
P.O. Box 12014  
2 T.W. Alexander Drive  
Research Triangle Park, NC 27709

**Re: Offer to Pay**

Dear Sir or Madam:

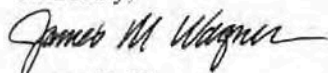
Rotam Limited is submitting a registration application to the U.S. Environmental Protection Agency ("EPA") for the product "Oxamyl Technical" containing Oxamyl as the active ingredient. This application relies on the cite-all method of support to satisfy generic data requirements. Your company is listed on the most recent EPA "Data Submitters List" for this active ingredient.

In accordance with the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") Section 3(c)(1)(F), Rotam Limited hereby offers to pay compensation after the approval of this application, to the extent required by Section 3(c)(1)(F) for specific and valid data for which your company is identified by the EPA as an original data submitter and on which this application relies. Rotam Limited offers to begin negotiations to determine which data are subject to the compensation regulations of FIFRA and the amount and terms of the compensation, if any, to be paid for any such data.

Further, if there are any studies that are in progress and that you are required to submit to EPA in response to a pending data call-in for Oxamyl, Rotam Limited hereby offers to jointly develop or share in the cost of developing such data.

For each study for which EPA which you seek compensation, you propose.

Sincerely,



James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com

#### SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Bayer Cropscience LP  
P.O. Box 12014  
2 T.W. Alexander Drive  
Research Triangle Park, NC 27709  
(Rotam Oxamyl 42% MUP) + Tech



9590 9402 2267 6225 8969 97

2. Article Number (Transfer from service label)

7016 2140 0001 1479 6111

#### COMPLETE THIS SECTION ON DELIVERY

A. Signature

☒ Agent  
☐ Addressee

B. Received by (Printed Name)

C. Date of Delivery

D. Is delivery address different from Item 1? If YES, enter delivery address below:

☐ Yes  
☒ No

3. Service Type

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- ☐ Adult Signature Restricted Delivery
- ☐ Certified Mail®
- ☐ Certified Mail Restricted Delivery
- ☐ Collect on Delivery
- ☐ Collect on Delivery Restricted Delivery

- ☐ Priority Mail Express®
- ☐ Registered Mail™
- ☐ Registered Mail Restricted Delivery
- ☐ Return Receipt for Merchandise
- ☐ Signature Confirmation™
- ☐ Signature Confirmation Restricted Delivery

**WRA**

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Bayer Cropscience LP  
P.O. Box 12014  
2 T.W. Alexander Drive  
Research Triangle Park, NC 27709

**Re: Offer to Pay**

Dear Sir or Madam:

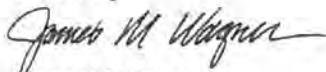
Rotam Limited is submitting a registration application to the U.S. Environmental Protection Agency ("EPA") for the product "Oxamyl 42% MUP" containing Oxamyl as the active ingredient. This application relies on the cite-all method of support to satisfy generic data requirements. Your company is listed on the most recent EPA "Data Submitters List" for this active ingredient.

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For each study for which EPA considers your company to be an original data submitter and for which you seek compensation, please identify the data items and any terms of compensation that you propose.

Sincerely,



James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com

# WRA

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Fifra Endangered Species Task Force  
c/o Compliance Services International  
7501 Bridgeport Way, West  
Lakewood, WA 98499

**Re: Offer to Pay**

Dear Sir or Madam:

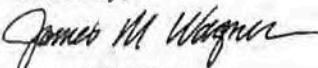
Rotam Limited is submitting a registration application to the U.S. Environmental Protection Agency ("EPA") for the product "Oxamyl Technical" containing Oxamyl as the active ingredient. This application relies on the cite-all method of support to satisfy generic data requirements. Your company is listed on the most recent EPA "Data Submitters List" for this active ingredient.

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Further, if there are any studies that are in progress and that you are required to submit to EPA in response to a pending data call-in for Oxamyl, Rotam Limited hereby offers to jointly develop or share in the cost of development of such studies. If you agree to this offer, please sign and return this card to the address below. If you do not agree, please return this card to the address below. If you have any questions, please contact the person listed below. This offer is valid until 12/31/2016.

For each study for which you seek compensation, please provide the following information on the back of this card or on a separate sheet of paper. If you have any questions, please contact the person listed below. This offer is valid until 12/31/2016.

Sincerely,

  
James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.co

## SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

### 1. Article Addressed to:

Fifra Endangered Species Task Force  
c/o Compliance Services International  
7501 Bridgeport Way, West  
Lakewood, WA 98499  
(Rotam Oxamyl 42% MUP) *F-Tech*



9590 9402 2267 6225 8969 73

### 2. Article Number (Transfer from service label)

7016 2140 0001 1479 6135

PS Form 3811, July 2015 PSN 7530-02-000-9053

## COMPLETE THIS SECTION ON DELIVERY

### A. Signature

*X* *Wagner Company* ☐ Agent ☐ Addressee

### B. Received by (Printed Name)

### C. Date of Delivery

D. Is delivery address different from item 1? ☐ Yes  
If YES, enter delivery address below: ☐ No

### 3. Service Type

- |  |   |
|--|---|
| <input type="checkbox"/> Adult Signature                         | <input type="checkbox"/> Priority Mail Express®                     |
| <input type="checkbox"/> Adult Signature Restricted Delivery     | <input type="checkbox"/> Registered Mail™                           |
| <input type="checkbox"/> Certified Mail®                         | <input type="checkbox"/> Registered Mail Restricted Delivery        |
| <input type="checkbox"/> Certified Mail Restricted Delivery      | <input type="checkbox"/> Return Receipt for Merchandise             |
| <input type="checkbox"/> Collect on Delivery                     | <input type="checkbox"/> Signature Confirmation™                    |
| <input type="checkbox"/> Collect on Delivery Restricted Delivery | <input type="checkbox"/> Signature Confirmation Restricted Delivery |
| <input type="checkbox"/> Mail Restricted Delivery                |   |

Domestic Return Receipt  
83



**WRA**

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Fifra Endangered Species Task Force  
c/o Compliance Services International  
7501 Bridgeport Way, West  
Lakewood, WA 98499

**Re: Offer to Pay**

Dear Sir or Madam:

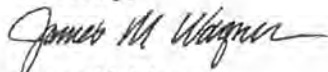
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Further, if there are any studies that are in progress and that you are required to submit to EPA in response to a pending data call-in for Oxamyl, Rotam Limited hereby offers to jointly develop or share in the cost of developing such studies to the extent required by FIFRA Section 3(c)(2)(B).

For each study for which EPA considers your company to be an original data submitter and for which you seek compensation, please identify the data items and any terms of compensation that you propose.

Sincerely,



James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com



# WRA

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Syngenta Crop Protection, LLC  
P.O. Box 18300  
410 Swing Road  
Greensboro, NC 27419

**Re: Offer to Pay**

Dear Sir or Madam:

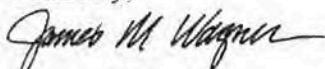
Rotam Limited is submitting a registration application to the U.S. Environmental Protection Agency ("EPA") for the product "Oxamyl Technical" containing Oxamyl as the active ingredient. This application relies on the cite-all method of support to satisfy generic data requirements. Your company is listed on the most recent EPA "Data Submitters List" for this active ingredient.

In accordance with the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") Section 3(c)(1)(F), Rotam Limited hereby offers to pay compensation after the approval of this application, to the extent required by Section 3(c)(1)(F) for specific and valid data for which your company is identified by the EPA as an original data submitter and on which this application relies. Rotam Limited offers to begin negotiations to determine which data are subject to the compensation regulations of FIFRA and the amount and terms of the compensation, if any, to be paid for any such data.

Further, if there are any studies that are in progress and that you are required to submit to EPA in response to a pending data callin for Oxamyl, Rotam Limited hereby offers to reimburse you or share in the cost of development of such studies, if you agree to do so, pursuant to Section 3(c)(2)(B).

For each study for which EPA requires you to submit data, you may seek compensation for the cost of development of such studies, if you agree to do so, pursuant to Section 3(c)(2)(B).

Sincerely,



James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.co

**SENDER: COMPLETE THIS SECTION**

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Syngenta Crop Protection, LLC  
P.O. Box 18300  
410 Swing Road  
Greensboro, NC 27419  
(Rotam Oxamyl 42% MUP) + Tech




9590 9402 1693 6053 6794 45

2. Article Number (Transfer from service label)

7016 2140 0001 1479 6166

**COMPLETE THIS SECTION ON DELIVERY**

A. Signature  ☐ Agent  
☒ Addressee

B. Received by (Printed Name) Steve McHenry C. Date of Delivery 12/5/16

D. Is delivery address different from item 1? ☐ Yes  
If YES, enter delivery address below: ☒ No

3. Service Type
- |  |   |
|--|---|
| <input type="checkbox"/> Adult Signature                         | <input type="checkbox"/> Priority Mail Express®                     |
| <input type="checkbox"/> Adult Signature Restricted Delivery     | <input type="checkbox"/> Registered Mail™                           |
| <input type="checkbox"/> Certified Mail®                         | <input type="checkbox"/> Registered Mail Restricted Delivery        |
| <input type="checkbox"/> Certified Mail Restricted Delivery      | <input type="checkbox"/> Return Receipt for Merchandise             |
| <input type="checkbox"/> Collect on Delivery                     | <input type="checkbox"/> Signature Confirmation™                    |
| <input type="checkbox"/> Collect on Delivery Restricted Delivery | <input type="checkbox"/> Signature Confirmation Restricted Delivery |
| <input type="checkbox"/> Mail Restricted Delivery                |   |

**WRA**

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Syngenta Crop Protection, LLC  
P.O. Box 18300  
410 Swing Road  
Greensboro, NC 27419

**Re: Offer to Pay**

Dear Sir or Madam:

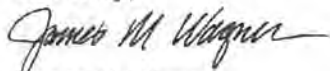
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Further, if there are any studies that are in progress and that you are required to submit to EPA in response to a pending data call-in for Oxamyl, Rotam Limited hereby offers to jointly develop or share in the cost of developing such studies to the extent required by FIFRA Section 3(c)(2)(B).

For each study for which EPA considers your company to be an original data submitter and for which you seek compensation, please identify the data items and any terms of compensation that you propose.

Sincerely,



James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com



# WRA

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Valent U.S.A. Corporation  
1600 Riviera Avenue, Suite 200  
Walnut Creek, CA 94596

**Re: Offer to Pay**

Dear Sir or Madam:

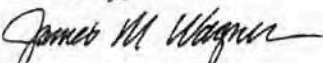
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For each study for which EPA requires data, which you seek compensation for, please complete this card and attach it to the back of the mailpiece, or on the front if space permits.

Sincerely,



James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com

**SENDER: COMPLETE THIS SECTION**

- ☒ Complete items 1, 2, and 3.
- ☒ Print your name and address on the reverse so that we can return the card to you.
- ☒ Attach this card to the back of the mailpiece, or on the front if space permits.

Valent U.S.A. Corporation  
1600 Riviera Avenue, Suite 200  
Walnut Creek, CA 94596  
(Rotam Oxamyl 42% MUP) *FTech*



9590 9402 1693 6053 6794 38

2. Article Number (Transfer from service label)

7016 2140 0001 1479 6173

PS Form 3811, July 2015 PSN 7530-02-000-9053

**COMPLETE THIS SECTION ON DELIVERY**

A. Signature

*X* 

☐ Agent  
☐ Addressee

B. Received by (Printed Name)

C. Date of Delivery

D. Is delivery address different from item 1? ☐ Yes  
If YES, enter delivery address below: ☐ No

**3. Service Type**

- |  |   |
|--|---|
| <input type="checkbox"/> Adult Signature                         | <input type="checkbox"/> Priority Mail Express®                     |
| <input type="checkbox"/> Adult Signature Restricted Delivery     | <input type="checkbox"/> Registered Mail™                           |
| <input type="checkbox"/> Certified Mail®                         | <input type="checkbox"/> Registered Mail Restricted Delivery        |
| <input type="checkbox"/> Certified Mail Restricted Delivery      | <input type="checkbox"/> Return Receipt for Merchandise             |
| <input type="checkbox"/> Collect on Delivery                     | <input type="checkbox"/> Signature Confirmation™                    |
| <input type="checkbox"/> Collect on Delivery Restricted Delivery | <input type="checkbox"/> Signature Confirmation Restricted Delivery |
| <input type="checkbox"/> Insured Mail                            |   |
| <input type="checkbox"/> Mail Restricted Delivery (00)           |   |

Domestic Return Receipt

**WRA**

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Valent U.S.A. Corporation  
1600 Riviera Avenue, Suite 200  
Walnut Creek, CA 94596

**Re: Offer to Pay**

Dear Sir or Madam:

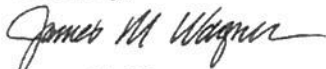
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For each study for which EPA considers your company to be an original data submitter and for which you seek compensation, please identify the data items and any terms of compensation that you propose.

Sincerely,



James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com



# WRA

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Agricultural Reentry Task Force  
Beveridge & Diamond, P.C.  
1350 I Street, NW  
Washington, DC 20005

**Re: Offer to Pay**

Dear Sir or Madam:

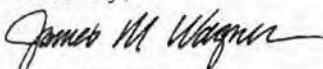
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Further, if there are any studies that are in progress and that you are required to submit to EPA in response to a pending data call-in for Oxamyl, Rotam Limited hereby offers to jointly develop or share in the cost of developing such studies to the extent required by Section 3(c)(2)(B).

For each study for which EPA considers your company which you seek compensation, please identify the data in your proposal.

Sincerely,



James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com

7016 2140 0001 1479 6104

U.S. Postal Service™ CERTIFIED MAIL® RECEIPT Domestic Mail Only	
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OFFICIAL USE	
Certified Mail Fee	\$
Extra Services & Fees (check box, add fee as appropriate)	
<input type="checkbox"/> Return Receipt (hardcopy)	\$
<input type="checkbox"/> Return Receipt (electronic)	\$
<input type="checkbox"/> Certified Mail Restricted Delivery	\$
<input type="checkbox"/> Adult Signature Required	\$
<input type="checkbox"/> Adult Signature Restricted Delivery	\$
Postage	\$
Total Postage and Fees	\$
Sent To	
Street and Apt. No., or PO Box No.	
City, State, ZIP+4®	
PS Form 3800, April 2015 PSN 7530-02-000-9047 See Reverse for Instructions	

**WRA**

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Agricultural Reentry Task Force  
Beveridge & Diamond, P.C.  
1350 I Street, NW  
Washington, DC 20005

**Re: Offer to Pay**

Dear Sir or Madam:

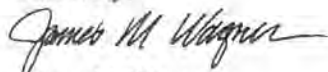
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In accordance with the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") Section 3(c)(1)(F), Rotam Limited hereby offers to pay compensation after the approval of this application, to the extent required by Section 3(c)(1)(F) for specific and valid data for which your company is identified by the EPA as an original data submitter and on which this application relies. Rotam Limited offers to begin negotiations to determine which data are subject to the compensation regulations of FIFRA and the amount and terms of the compensation, if any, to be paid for any such data.

Further, if there are any studies that are in progress and that you are required to submit to EPA in response to a pending data call-in for Oxamyl, Rotam Limited hereby offers to jointly develop or share in the cost of developing such studies to the extent required by FIFRA Section 3(c)(2)(B).

For each study for which EPA considers your company to be an original data submitter and for which you seek compensation, please identify the data items and any terms of compensation that you propose.

Sincerely,



James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com

# WRA

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 30, 2016

Spray Drift Task Force  
McKenna, Long & Aldridge LLP  
1900 K Street, NW  
Washington, DC 20006

**Re: Offer to Pay**

Dear Sir or Madam:

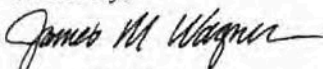
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Sincerely,



James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com

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For each study for which EPA considers your company to be an original data submitter and for which you seek compensation, please identify the data items and any terms of compensation that you propose.

Sincerely,

A handwritten signature in black ink, reading "James M. Wagner".

James M. Wagner  
Agent for Rotam Limited  
Telephone: 302-635-7290  
Email: james@wagnerreg.com





Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

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Pesticide Data Submitters List:

By Active Chemical Code -Jan 11, 2017 Edition

TECH

CHEMICAL CHEMICAL NAME

103801 Oxamyl

OXAMYL -  
NO EXU IN  
PDSL.

Company # Company Address

100 SYNGENTA CROP PROTECTION, LLC  
P.O. Box 18300  
410 SWING ROAD  
GREENSBORO, NC 27419

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									

Company # Company Address

264 BAYER CROPSCIENCE LP  
P.O. Box 12014  
2 T.W. ALEXANDER DRIVE  
RESEARCH TRIANGLE PARK, NC 27709

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									

Company # Company Address

352 E. I. DU PONT DE NEMOURS AND COMPANY (ATTN: MANAGER, US REGISTRATION, DUPONT CHESTNUT RUN PLAZA, 974 CENTRE ROAD, PO BOX WILMINGTON, DE 19805

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y	Y			Y	Y	Y	Y	Y	Y

Company # Company Address

59639 VALENT U.S.A. CORPORATION  
1600 RIVIERA AVENUE, SUITE 200  
WALNUT CREEK, CA 94596

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									

Company # Company Address

66607 SPRAY DRIFT TASK FORCE  
MCKENNA, LONG & ALDRIDGE LLP  
1900 K STREET, NW  
WASHINGTON, DC 20006

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

71755 AGRICULTURAL REENTRY TASK FORCE  
BEVERIDGE & DIAMOND, P.C.  
1350 I STREET, N.W.  
WASHINGTON, DC 20005

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

73989 FIFRA ENDANGERED SPECIES TASK FORCE, L  
C/O COMPLIANCE SERVICES INTERNATIONAL  
7501 BRIDGEPORT WAY, WEST  
LAKEWOOD, WA 98499

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC

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### Petitions Requesting to Extend the Exclusive Use Period for an Active Ingredient

#### Petitions Requesting to Extend the Exclusive Use Period for an Active Ingredient - FIFRA § 3(c)(1)(F)(ii)

Find more information about exclusive use periods.

Chemical	Date Request Received	Date of Response	Granted/Denied	End Date for Exclusive Use
Acetamiprid	8/11/2008	4/6/2010	Granted	3/15/2012
	6/2/2009			
Azoxystrobin	9/1/2006	1/16/2009	Granted	2/7/2010
Boscalid	8/2/2007	11/21/2011	Granted	7/23/2016
Buprofezin	9/2007	8/20/2012	Granted	9/7/2013

Chemical	Date Request Received	Date of Response	Granted/ Denied	End Date for Exclusive Use
Carfentrazone-ethyl	4/14/2008	9/9/2009	Granted	9/30/2010
		10/4/2011	Granted	9/30/2011
Chlorantraniliprole (Rynaxypyr)	1/5/2011	1/14/2016	Granted	4/25/2021
	1/29/2007	Superseded by 1/5/2011		
Clethodim	4/28/2000	9/27/2000		
Clothianidin	11/11/2011	8/16/2012	Granted	5/30/2016
Cyantraniliprole	3/14/2014	7/16/2015	Granted	1/24/2027
Cyazofamid	9/4/2013	9/25/14	Granted	11/9/2017
	9/6/2013			
Cymoxanil	10/19/2007	11/16/2010	Granted	5/6/2009
Cyprodinil	2/1/2008	4/21/2010	Granted	4/10/2010
Dinotefuran	5/13/2013	2/28/2014	Granted	9/17/2017
Etoxazole	8/11/2010	4/20/2012	Granted	8/22/2015
Famoxadone	10/19/2007	Pending		
	5/12/2009	12/8/2009	Denied	
Fenhexamid		6/19/2006	Denied	
Fenpyroximate	9/9/2013	11/25/2014	Granted	4/27/2017



<b>Chemical</b>	<b>Date Request Received</b>	<b>Date of Response</b>	<b>Granted/Denied</b>	<b>End Date for Exclusive Use</b>
Fluazinam	10/15/2010	8/9/2011	Granted	8/10/2014
Fludioxonil	1/29/2004	11/1/2005	Granted, In Part	10/5/2007
Flumioxazin	8/15/2008	12/16/2008	Granted	4/12/2014
Forchlorfenuron	10/17/2014	1/8/2016	Withdrawn	2/2/2015
Indoxacarb	10/16/2007	9/10/2009	Granted	10/30/2013
Mesotrione	1/15/2009	5/11/2012	Granted	6/4/2014
Metconazole	12/27/2013	1/20/2015	Granted	9/28/2020
Prothioconazole	5/5/2014	6/3/2015	Granted	3/27/2020
Pyraclostrobin	8/2/2007	1/11/2012	Granted	9/30/2015
Pyriproxyfen	4/11/2002	6/21/2004	Granted	9/15/2008
Quinoxifen	7/2/2008	Pending		
S-metholachlor	2/15/2005	9/15/2009	Denied	9/15/2009
Saflufenacil	12/15/2014	01/05/2016	Granted	9/03/2022
Spinetoram	12/1/2015	12/1/2016	Granted	9/28/2020
Spinosad	9/19/2003	10/22/2010	Granted	8/30/2010
Spirodiclofen	10/17/2012	7/19/2013	Granted	6/30/2018
Spiromesifen	11/14/2007	9/10/2009	Granted	5/3/2018

<b>Chemical</b>	<b>Date Request Received</b>	<b>Date of Response</b>	<b>Granted/Denied</b>	<b>End Date for Exclusive Use</b>
Spirotetramat	9/23/2013	12/19/2014	Granted	2/4/2022
Sulfentrazone	7/26/2006	6/11/2007	Granted	2/27/2009
Tetraconazole	5/19/14	4/8/2015	Granted	4/14/2016

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# Petitions Filed to Establish New Exclusive Use Periods for a Specific Commodity

Current as of April 2016

Petitions Filed to Establish a New Exclusive Use Period for a Specific Commodity- FIFRA § 3(c)(1) (F)(vi)

Find more information about exclusive use periods.

Chemical	Date Request Received	Date of Response	Granted/Denied	End Date for Exclusive Use
Cyprodinil	12/2/2014	4/1/2016	Denied	
	3/31/2015	5/11/2016	Denied	
Deltamethrin	9/6/2013	3/11/2016	Partially Granted	9/19/2023
Difenoconazole	10/3/2006	8/29/2013	Granted	10/3/2016
	12/18/2009	8/29/2013	Granted	12/18/2019



Chemical	Date Request Received	Date of Response	Granted/Denied	End Date for Exclusive Use
	12/26/2013 10/29/2014	6/1/2015	Partially Granted	10/29/2024
Fenpropathrin	3/15/2005	9/25/2006	Denied	
Halosulfuron	6/3/2009	9/10/2009	Denied	
Fluridone	8/29/2014	2/12/2016	Granted	8/29/2024
Quinoxifen	7/2/2008	9/25/2009	Denied	
Thiabendazole	2/19/2014	9/25/2014	Granted	3/18/2023

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# Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
81598-XX	November 21, 2016	81598-XXXXXX.20161121.V1

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

  
Signature

November 21, 2016  
Date

James Wagner  
Name (typed)

Agent for Rotam Limited  
Title

# Oxamyl Technical

## INSECTICIDE/NEMATICIDE

### ACTIVE INGREDIENT:

Oxamyl

Methyl N,N'-dimethyl-N-[(methylcarbamoyl)oxy]-1-thiooxamimidate..... 97.41%

OTHER INGREDIENTS: ..... 2.59%

TOTAL: ..... 100.0%

BY WT.

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER/PELIGRO**



**POISON/VENENO**

### FIRST AID

**Contains an N-methyl carbamate that inhibits cholinesterase.**

<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger.</li> <li>• Do not induce vomiting or give anything by mouth to an unconscious person.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF INHALED:</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>

### ATROPINE IS AN ANTIDOTE: SEEK MEDICAL ATTENTION AT ONCE IN ALL CASES OF SUSPECTED POISONING

If symptoms appear (see **SYMPTOMS**), get medical attention.

**SYMPTOMS:** Oxamyl poisoning produces effects associated with anticholinesterase activity which may include weakness, blurred vision, headache, nausea, abdominal cramps, discomfort in the chest, constriction of pupils, sweating, slow pulse, muscle tremors.

### NOTE TO PHYSICIAN

**TREATMENT:** Atropine sulfate should be used for treatment. Administer repeated doses, 1.2 to 2.0 mg intravenously every 10 to 30 minutes until full atropinization is achieved. Maintain atropinization until the patient recovers. Artificial respiration or oxygen may be necessary. Allow no further exposure to any cholinesterase inhibitor until recovery is assured. Do not use morphine or 2-PAM.

### HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For 24-Hour Medical Emergency Assistance (Human or Animal), call: **1-800-222-1222**. For Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), call CHEMTREC: **1-800-424-9300**.

### Manufactured For:

Rotam Limited  
Unit 6, 26/F Trend Centre  
29 Lee Chung Street  
Chai Wan, Hong Kong

EPA Reg. No.: 81598-XX  
EPA Est. No.:

Net Contents:



**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS & DOMESTIC ANIMALS  
DANGER/POISON**

Fatal if swallowed. May be fatal if inhaled. Harmful if absorbed through skin. Do not breathe vapor. Do not get in eyes, on skin or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**HANDLE PRODUCT ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT:**

Wear a protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet. Wear chemical-resistant gloves, chemical-resistant apron and chemical-resistant shoes, shoe coverings or boots. Wear goggles or a face shield. Wear a pesticide respirator approved by the National Institute for Occupational Safety and Health (NIOSH) and the Mine Safety and Health Administration (MSHA). Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to aquatic organisms and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**PHYSICAL AND CHEMICAL HAZARDS**

Combustible. Do not use or store near heat or open flame. Keep container closed. Use with adequate ventilation.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Only for formulation into an insecticide/nematicide.

**For the following uses:**

**Terrestrial Food Crops:**

- |  |  |
|--|--|
| ◦ apples, apples (non-bearing),                      | ◦ peppers, bell and non-bell                 |
| ◦ bananas,   | ◦ peppermint,                                |
| ◦ cantaloupe,  | ◦ pineapple,                                 |
| ◦ carrots,   | ◦ plantain,                                  |
| ◦ celery,  | ◦ potato,                                    |
| ◦ cherry (non-bearing),                              | ◦ pumpkin,                                   |
| ◦ citrus (group 10), citrus (non-bearing) (group 10) | ◦ spearmint,                                 |
| ◦ cotton,  | ◦ squash,                                    |
| ◦ cucumber,  | ◦ tomato,                                    |
| ◦ eggplant,  | ◦ Tuberous and corm vegetables (subgroup 1C) |
| ◦ garlic,  | ◦ watermelons                                |
| ◦ ginger,  |  |
| ◦ honeydew   |  |
| ◦ melons,  |  |
| ◦ onions (dry bulb),                                 |  |
| ◦ peach (non-bearing),                               |  |
| ◦ peanuts,   |  |
| ◦ pear, pear (non-bearing),                          |  |

**Terrestrial Non-Food Crops: Tobacco**

- Uses for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration
- Uses for experimental purposes that are in compliance with U.S. EPA requirements.

Products formulated from this product will require registration with the Environmental Protection Agency.

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

### **Pesticide Storage**

Store product only in original container, in a cool, dry industrial location inaccessible to children and pets. Do not use or store in or around the home.

### **Pesticide Disposal**

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**NONREFILLABLE CONTAINERS:** Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Offer for recycling, if available.

## CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

**NOTICE:** Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of this product, which are beyond the control of ROTAM LIMITED, or Seller. The Buyer and User shall assume all such risks, and Buyer and User agree to hold ROTAM LIMITED and Seller harmless for any claims relating to such factors.

To the extent consistent with applicable law, ROTAM LIMITED warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to proper instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or ROTAM LIMITED, and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ROTAM LIMITED MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR NEITHER A PARTICULAR PURPOSE NOR ANY OTHER EXPENSES OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with applicable law, ROTAM LIMITED or Seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF ROTAM LTD AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF ROTAM LIMITED OR SELLER, THE REPLACEMENT OF THE PRODUCT.

ROTAM LIMITED and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sales and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of ROTAM LIMITED.

# Certification with Respect to Label Integrity

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Signature

November 21, 2016  
Date

James Wagner  
Name (typed)

Agent for Rotam Limited  
Title



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

November 30, 2016

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

WAGNER REGULATORY ASSOCIATES, INC.  
ROTAM LIMITED  
7217 LANCASTER PIKE, SUITE A  
PO.BOX : 640  
HOCKESSIN, DE 19707

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 22-NOV-16. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

November 28, 2016

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-523784  
EPA File Symbol or Registration Number: 81598-RT  
Product Name: Oxamyl Technical  
EPA Receipt Date: 22-Nov-2016  
EPA Company Number: 81598  
Company Name: ROTAM LIMITED

JAMES WAGNER  
WAGNER REGULATORY ASSOCIATES, INC.  
AGENT FOR ROTAM LIMITED  
PO BOX 640  
HOCKESSIN, DE 19707-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R333

NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF THE ACTIVE INGREDIENT;REQUIRES SCIENCE DATA REVIEW;NEW PHYSICAL FORM;CITE-ALL OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "mjh", is written over the word "Sincerely,".

Front End Processing Staff  
Information Technology & Resources Management Division

## Fee for Service

{995323&~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 10

Receipt No.

S- 995323

EPA File Symbol/Reg. No.

81598-RT

Pin-Punch Date:

11/22/2016

This item is NOT subject to FFS action.

### Action Code:

Requested: R333

Granted: R333

Amount Due: \$ 19,838.00

### Parent/Child Decisions:

S- 995323

81598-RT

children: S995292 83100-LE  
S995320 83100-LG  
S995318 81598-RA

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: L. Roe

Date: 11/23/2016

Remarks:

S: 995323

Milestone Email: jmw@wagnerreg.com

Regulatory Type: Product Registration - Section 3

Resubmit(s):

Yes No

Print Letter

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Enter More Information

Company: 81598 ROTAM LIMITED

Billable: ☒ Yes ☐ No

Tracking

V

Risk Manager: Registration Division, Risk Management Team 10

Product #: 81598-RT

Product Name: Oxamyl Technical

Chemical

☒ Me Too Section 3: 352-400

Me Too Product Name: DUPONT OXAMYL TECHNICAL 42 INSECTICI ...

Application Date: 21-Nov-2016



OPP Rec'd Date: 22-Nov-2016



Front End Date: 23-Nov-2016



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Study

CSF

View/Edit

File Trace:

New Ingredient:

Receipt Description:

Portal submission pkg. #15645: Registration of a new technical product containing the registered active ingredient Oxamyl.

New Ingredient

Request Date

New Ingredient

Received Date

Form

Signature Date

Form B

Signature Date

**From:** notification@pay.gov  
**To:** [Anna Armstrong](#)  
**Subject:** Pay.gov Payment Confirmation: PRIA Service Fees  
**Date:** Tuesday, November 22, 2016 8:32:59 AM

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Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or [yanchulis.michael@epa.gov](mailto:yanchulis.michael@epa.gov).

Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 25V4M26V  
Agency Tracking ID: 75133912881  
Transaction Type: Sale  
Transaction Date: 11/22/2016 08:32:50 AM EST

Account Holder Name: Cheryl R. Wagner

Transaction Amount: \$19,838.00  
Card Type: AmericanExpress  
Card Number: \*\*\*\*\*2008

Registration Number:  
Company Name: Rotam Limited  
Company Number: 81598  
Action Code: R333

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 11-22-16

Experts In-Processing Signature: B.B. Date 11-28-16 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>81598-RT</u>		EPA Receipt Date: <u>11-22-16</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A) <i>No inerts to review</i>	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
		X				
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

**Comments:**

Documentation Pass or Fail  
 - All Required Forms Complete

Inerts Pass or Fail  
 - Technical, Inerts, and Water Only,  
 No Inerts to Review

PRN 11-03 Pass or Fail  
 - MRID: 500378

24/1/16

Overall Status Pass or Fail

\* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.



During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### **Conventional New Product Applications**

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)



3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

\*Confidential Statement of Formula may be entitled to confidential treatment\*